PUTTING HIV AND HCV TO THE TEST

A PRODUCT GUIDE FOR POINT-OF-CARE CD4 TESTS AND LABORATORY-BASED AND POINT-OF-CARE HIV AND HCV VIRAL LOAD TESTS

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ADDITIONAL RESOURCES ON HIV AND HCV

PREVIOUS EDITIONS OF THIS REPORT

Putting HIV and HCV to the Test 2015 – A product guide for point-of-care CD4 and laboratory-based and point-of-care virological HIV and hepatitis C virus (HCV) tests.

Supplementary Material: National recommendations on infant diagnosis, testing of pregnant and breast-feeding women, CD4, and viral load testing, across 55 low- and middle-income countries, sourced from the IAPAC database.

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Putting HIV Treatment to the Test 2013 – A product guide for viral load and point-of-care CD4 diagnostic tools.

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HIV: UNDETECTABLE

The MSF Access Campaign has published a series of briefing documents to equip policymakers, people living with HIV/AIDS, and communities with information about the products, costs and operational strategies needed to help scale-up viral load monitoring, which is an essential tool, along with adherence support, to help as many people on ARVs as possible to reach and maintain viral suppression. MSF's **HIV: Undetectable** reports provide detailed information on HIV viral load testing, including pricing information, in-country market assessments, and training and implementation tools.

Volume 1 – **Undetectable: How Viral Load Monitoring Can Improve HIV Treatment in Developing Countries**

Volume 2 – **Putting HIV Treatment to the Test: A Product Guide for Viral Load and Point-of-Care CD4 Diagnostic Tools**

Volume 3 – **How Low Can We Go? Pricing for HIV Viral Load Testing in Low- and Middle-Income Countries**

Volume 4 – **HIV Status? Undetectable: Four Essential Interventions to Improve HIV Treatment, Save Lives, and Reduce Transmission**

Volume 5 – **Getting to Undetectable: Usage of HIV Viral Load Monitoring in Five Countries**

Volume 6 – **Achieving Undetectable: What Questions Remain in Scaling-Up HIV Virologic Treatment Monitoring?**

Volume 7 – **Putting HIV and HCV to the Test: A Product Guide for Point-of-Care CD4 and Laboratory-based and Point-of-Care Virological HIV and HCV Tests**

Volume 8 – **Making Viral Load Routine: Successes and Challenges in the Implementation of Routine HIV Viral Load Monitoring**

Viral Load Toolkit – **An Implementer's Guide to Introducing HIV Viral Load Monitoring from MSF's Southern Africa Medical Unit**

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UNTANGLING THE WEB OF ANTIRETROVIRAL PRICE REDUCTIONS

For more than 15 years, the MSF Access Campaign has been monitoring the patent barriers, prices and availability of antiretroviral medicines through its Untangling the Web reports and pushing for the uptake of policies that promote access to affordable, quality-assured treatments.

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INTRODUCTION

This report is a guide for policymakers, treatment providers and advocates interested in learning more about diagnostic and monitoring tests for HIV and hepatitis C virus (HCV), including both laboratory-based and point-of-care virological tests, and point-of-care CD4 tests.

Although global access to antiretroviral treatment (ART) has substantially increased, in mid-2016 only about half of the 36.7 million people living with HIV had been started on ART;[1] only 60 percent of HIV-positive people know their status, and there are still 1.1 million AIDS-related deaths per year.[2]

Two of the three UNAIDS "90/90/90" goals (by 2020, 90% of people will know their status; 90% of HIV-positive people will receive sustainable ART; and 90% of those on ART will be virally suppressed) rely on access to diagnostic and monitoring tools, including CD4 cell testing to identify severe immunosuppression in patients presenting with advanced disease, life-saving early infant diagnostics (EID), and routine HIV viral load (VL) monitoring. Yet access to World Health Organization (WHO)-recommended standards of care, including routine VL monitoring, is inadequate. It is imperative that affordable and adapted HIV diagnostic tests be made fully available in resource-limited settings.

Oral direct-acting antivirals (DAAs) – and their simpler diagnostic and monitoring requirements – will transform the ability to treat the 71 million people who have chronic HCV infection.[3] Currently, high prices limit access to DAAs and diagnostics; as of 2016, only one million people in low- and middle-income countries (LMIC), home to 70% of people with HCV[3], had been treated.[4] As with HIV, increased access to and scale-up of HCV treatment and affordable, adapted diagnostic tools is urgently required, especially for the 2.3 million HIV/ HCV coinfected people[4] who are at risk for accelerated liver disease progression and higher mortality.[5]

Putting HIV and HCV to the Test includes technical specifications and pricing information for 22 diagnostic platforms comprising 48 test products. See inside front cover for information on prior editions of this report.

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MSF AND HIV DIAGNOSTIC AND MONITORING TOOLS

In 2015, MSF provided ART to 240,000 HIV-positive people in 18 countries.[6] MSF is an early adopter of HIV VL, point-of-care (POC) and EID testing in resource-limited settings, and is currently field-testing or evaluating these technologies in a number of countries.

With support from UNITAID, MSF has been implementing a four-year project to evaluate various VL, EID and CD4 testing technologies in ten projects, across nine countries. As part of this project, MSF has produced a series of resources to support and guide countries as they embark into rolling-out VL testing; this includes a VL toolkit with training material,[7] as well as practical lessons learnt from the HIV VL initiative.[8]

MSF field teams, in collaboration with Ministries of Health, have made great strides to begin the scale up of VL testing, and in developing models of care that optimize the use and benefits of VL. As a result of the project, more HIV-positive people on ART have access to VL testing, adherence counselling and second-line treatment.

Although the project has demonstrated that implementation of routine VL monitoring is feasible in resource-limited settings, it also highlights that there is a long way to go before we can reach the 90-90-90 global targets. In particular, innovative ways to identify people who are experiencing HIV treatment failure and increase initiation of second-line HIV treatment are urgently needed.

New WHO guidelines for EID recommend the addition of nucleic acid testing at birth and testing closer to the patient using new POC technologies.[7] MSF is field-testing three new POC EID technologies (AlereQ, SAMBA and Xpert) in the Democratic Republic of Congo, Kenya, Malawi, South Africa, Uganda and Zimbabwe. MSF is comparing their diagnostic performance to laboratory-based methods, while demonstrating the feasibility of decentralized testing at the primary healthcare level. This research will also assess the impact of birth testing and expanded EID screening outside of PMTCT sites on rates of testing coverage, timely treatment initiation and retention in care.

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SNAPSHOT OF IMPLEMENTATION OF HIV TESTING GUIDELINES

This report includes a brief summary of implementation of WHO HIV testing guidelines in low-and-middle income countries. For a more detailed look at this information, please review supplementary material published at: www.msfaccess.org/PHHT2017. National HIV testing guidelines can also be found at the IAPAC website: www.hivpolicywatch.org.

EARLY INFANT DIAGNOSIS

Most EID national guidelines reflect WHO 2016 guidelines for initial HIV testing in infants between 4-6 weeks of age.

- In a number of countries, guidelines recommend earlier testing: Colombia, Chile and Mexico recommend EID testing 48 hours after birth and Morocco at 1 week after birth.
- Seven countries have changed their national guidelines to include birth testing as recommended in the 2016 WHO guidelines: Burundi, Cambodia, Kenya, Namibia, South Africa, Zambia and Zimbabwe.

CD4 AND VIRAL LOAD

The national guidelines from 51 of 54 lower- and middle-income countries recommend routine VL monitoring for people on ART, in line with WHO recommendations. However, in reality, VL testing is only available in a handful of countries. In countries where VL testing is available, the systems and clinical capacity to promptly act on the results are rarely in place.

- Three countries recommend VL testing only in the case of suspected treatment failure – this testing is mandatory in Morocco, Myanmar and South Sudan (if the test is available).
- Most countries are still recommending routine CD4 cell treatment monitoring, with only 13 countries having dropped it post-ART initiation (Burundi, Cameroon, Kenya, Malawi, Malaysia, Mozambique, Namibia, Rwanda, South Africa, Swaziland, Thailand, Uganda and Zambia).
- Twenty-one countries do not recommend CD4 testing for treatment initiation.

WHY CD4 TESTING IS STILL NEEDED

Since WHO guidelines now recommend HIV treatment for all, regardless of CD4 cell count,[9] and routine VL testing is being scaled-up, more countries are discontinuing CD4 cell testing. But CD4 determination is still important for identifying patients with advanced HIV disease who may require prophylaxis against opportunistic infections. Management of advanced HIV disease is still a priority: MSF clinicians continue to note an unacceptable proportion of deaths among patients who present with low CD4 cell counts either at ART initiation or while already on ART. A minimal screening package for primary health clinics should include simple and affordable diagnostic tools such as POC CD4, TB-LAM, CrAg LFA and referral for Xpert MTB/RIF and VL testing- and access to life-saving drugs. Countries should be working towards its implementation.

UPDATED GLOBAL FUND TENDER ON EID AND VIRAL LOAD

The results of the first three-year tender issued by the Global Fund to Fight AIDS, TB, and Malaria (GFATM) for EID and VL were released in June 2015. The Global Fund's supplier panel was recently updated to include two new entrants in the market, Biocentric and Diagnostics for the Real World. Price lists have also been updated.

As of April 2017, at a 300,000 test volume price break, the total cost of ownership (TCO) for viral load ranges from US$11.47 to $32 per test, and for EID, from $17-43 per test. TCO includes reagents, controls, calibrators and consumables; equipment, servicing and set-up, and all logistics. Although the TCOs have not achieved lower pricing than already offered, many countries were paying much higher prices when they purchased tests through the Global Fund – up to around $40 per test, all-inclusive. Further information may be accessed at: www.theglobalfund.org/media/5765/psm_viralloadearlyinfantdiagnosis_content_en.pdf. Countries that had previously been excluded from more affordable pricing will benefit substantially.

Fortunately, reagent rental options are now available from the majority of suppliers, which was not previously the case, and there is no price premium for countries to select this option. Across standard instrument purchase and reagent rental options, manufacturers offered TCOs, either with volume discounts or price breaks (i.e. a reduced unit price once price break points have been achieved) or committed volumes (i.e. reduced unit price for all units committed in advance).

- Alere, bioMérieux, Cepheid, DRW, Hologic and Qiagen offered price breaks for standard purchase, and Hologic and Qiagen offered them for reagent rental.
- Abbott, Alere, Biocentric, bioMérieux, Cepheid, Hologic and Qiagen offered committed volume pricing for standard purchase; Abbott, Biocentric, bioMérieux, Hologic, Qiagen and Roche offered them for reagent rental (only Roche offered pricing irrespective of volume for both standard purchase and reagent rental).

Fortunately, the tender also applies to legacy countries and machines that are already in place. The tender has already resulted in more pricing transparency and increased competition between manufacturers, among other advantages. Future tenders should include the option for manufacturers of polyvalent platforms to submit bundled TCO discounts across disease-specific testing platforms (for example, TB and HCV), and the criteria for the tender should be transparent.

MSF AND HCV

In 2013, MSF began treating HCV-infected patients in Iran and Pakistan. In 2014, with the advent of interferon-free treatment, MSF started integrating HCV treatment into HIV care in India, Kenya, Mozambique and Myanmar. These projects were facilitated by a UNITAID grant beginning in 2015. Today, MSF has HCV projects in twelve countries, now including Belarus, Cambodia, Ukraine and Uzbekistan. The objective is to scale up DAA treatment, since it has simplified diagnostic and monitoring algorithms, and, for the first time, made treating HCV feasible in resource-limited settings.


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AFFORDABLE AND RELIABLE DIAGNOSTICS: KEY TO SCALE-UP HCV PROGRAMMES

Of the estimated 71 million people living with chronic HCV, only an estimated 20% are aware of it.[3] Lack of national guidelines and limited access to testing remain a bottleneck, both for gauging the burden of disease, and for planning effective implementation and scale-up of HCV treatment programmes.

Rapid diagnostic tests (RDTs) are critical to facilitate decentralized HCV testing programmes. Although quality-assured ELISA-based methods are available, they require laboratory facilities and may hamper uptake of testing in resource-limited settings (RLS). Recently, two HCV RDTs received WHO prequalification (WHO-PQ), the SD Bioline (Standard Diagnostics, Korea) and OraQuick (OraSure, USA). The latter, however, remains too costly ($7 versus $1per test) for use in RLS. There is an urgent need to further expand the list of HCV RDT options to foster competition and create a more healthy market.

There are concerns about the performance of HCV RDTs in certain populations. An MSF evaluation found a lower sensitivity of the OraQuick RDT in HIV-positive individuals.[10] Therefore, RDTs need additional field diagnostic performance evaluations in key populations. Self-testing has been proposed as an alternative to enable community-based testing, but currently, there are no HCV home self-tests available in the market.

The presence of HCV antibodies can reflect past or current infection, so confirmatory testing is required to ascertain active HCV infection. Nucleic acid testing (NAT) is recommended, both to confirm active infection and as a test-of-cure (sustained virologic response; SVR) at 12 weeks after treatment completion (SVR-12; when HCV RNA becomes undetectable during treatment and remains undetectable 12 weeks after treatment is finished). Several laboratory-based platforms are commercially available, including from Abbott, Biocentric, Hologic and Roche, among others. But the high prices for these tests impede large-scale implementation; they are a significant part of the expense for the full diagnostic and treatment package. The lack of international funding for HCV diagnostics has kept the volume of testing low, which in turn, makes it harder to negotiate better pricing.

Because HCV confirmatory testing is currently confined to central laboratories, there are long delays before results are delivered, which is a barrier to testing in RLS. Simpler diagnostics adapted to the district or primary healthcare level will be instrumental for decentralising testing, such as dried blood spots (DBS) and near point-of-care technologies. Manufacturers of lab-based platforms will have to validate the use of DBS. To date, there is no a single company with DBS regulatory approval for their existing commercial assays, despite independent evaluations that have demonstrated acceptable performance. The near-POC GeneXpert HCV RNA test has recently been WHO-prequalified and is an important step towards decentralized testing. But performance of the test in genotypes 5 and 6 remains poorly documented; additional local evaluations will be needed before it can be rolled out in settings with a high prevalence of these genotypes. The POC Genedrice HCV test is currently undergoing CE-marking, and is expected to be launched in mid-to-late 2017.

Continued overleaf

The test is relatively simple to perform, although it requires plasma, which may limit its use in primary health clinics without centrifuges.

The ELISA-based hepatitis C core antigen test (HCVcAg) might be a low-cost alternative to NAT-based assays. Although ELISA tests should be more affordable than NAT technologies, the cost of the laboratory-based assay from Abbott (Architect) is highly variable, and often country-specific, ranging from $10-50 per test[11]. A true point-of-care HCVcAg assay (Daktari) is undergoing clinical evaluations; the launch is expected in 2018 (so it is therefore not included in this report); the price is unknown. If the test is cheap enough, it would allow further simplification of testing through a one-step approach (obviating the need for separate antibody and NAT-based testing), particularly in high prevalence settings or for high-risk groups, where it could be more cost-effective.

The introduction of effective, pan-genotypic, interferon-free direct-acting antiviral (DAA) treatment for HCV simplifies diagnostics and monitoring during and after treatment. (See Table 1). Access to affordable DAAs is essential for global roll out, since the HCV diagnostic and monitoring package remains complex - and costly - in countries that only provide interferon and ribavirin (a less effective treatment that has debilitating side effects). Treatment without DAAs requires multiple virological tests to monitor treatment effectiveness. In addition, pre-treatment HCV genotyping must be performed to determine duration, and the extent of liver fibrosis must be measured; also, toxicity monitoring is needed during treatment. This package - including treatment - costs between $500 and $600 per patient. Countries have had to limit access to high-priced DAAs by prioritizing patients with the most advanced liver damage; this means that everyone with HCV must undergo liver disease staging, which is inefficient and costly.

TABLE 1: CURRENT WHO TESTING ALGORITHM ACCORDING TO TYPE OF HCV TREATMENT REGIMEN

TIME	DAA ALONE				DAA + RIBAVIRIN				DAA + PEG-IFN + RIBAVIRIN		
	Antibody screening	FBC, renal and liver function	Adherence, side effects	HCV RNA	Antibody screening	FBC, renal and liver function	Adherence, side effects	HCV RNA	Antibody screening	FBC, creatinine, ALT	Thyroid function
Baseline	x	x		x	x	x		x	x	x	x
Week 1						x	x			x	
Week 2						x	x			x	
Week 4		x	x			x	x			x	
Week 8						x	x			x	
Week 12						x	x			x	x
Week 12 post-treatment				x		x		x		x	x
Week 24 post-treatment											

Source: WHO Guidelines for the screening, care and treatment of persons with chronic hepatitis C infection. Updated version. [Online] April 2016 [Cited 2017 June 13] Available from: http://apps.who.int/iris/bitstream/10665/205035/1/9789241549615_eng.pdf?ua=1

THE PRODUCT GUIDE FINDINGS – IN BRIEF

This report compiles information that manufacturers were willing to share about their commercially available products. A few pipeline products were included, if pricing and other information was made available.

CD4 POINT-OF-CARE TESTS

The currently available POC CD4 tests are priced quite competitively, within the US$3–12 range per test (Table 2).

- The BD FACSPresto is priced higher (at around $10 per test) but it delivers CD4 count, CD4 percentage and haemaglobin results.
- The Alere Pima Analyser, which is well-established and fairly widely implemented, is currently priced at around $6 per test.
- The Sysmex Partec CyFlow miniPOC measures both CD4 count and percentage, and is the most affordable option at $3.15 per test. It also offers higher throughput than the other tests, and thus may be useful at district level.
- The Omega Diagnostics Visitect CD4 test is a semi-quantitative, disposable, instrument-free test coming to the market in 2017; it will be priced at around $5 a test.
- The Millipore Muse delivers both the CD4 count and percentage and has an indicative price of $5 per test. The system is now available for sale in 14 countries.

In some countries, POC CD4 testing will still be used for treatment initiation, depending on how quickly they adopt the WHO 'test-and-treat' guidelines and implement routine viral load testing. However, baseline CD4 testing remains important for assessing immunosuppression in patients presenting with advanced HIV disease (and potentially as a triggered test during treatment failure); therefore, demand for CD4 cell testing will continue.[12, 13]

TABLE 2:

POINT-OF-CARE CD4 TESTS	COST PER TEST IN USD[1]
Alere Pima Analyser *Well-established and fairly widely implemented in resource-limited settings; cartridge-based*	**$6 – 12**
BD FACSPresto *Market launched and quality assured, fully decentralisable, batching is possible; measures CD4 count, CD4 % and Hb; cartridge-based*	**<$10**
Millipore Muse Auto CD4/CD4% system *Commercially available; measures both CD4 count and CD4 %; flow cytometry-based*	**~$5**
Omega Visitect CD4 *Not yet commercially available; disposable, instrument-free, semi-quantitative, lateral flow test; currently at 350 cells/µL but intend to offer 200 cells/µL in the future*	**$5.20**
Sysmex Partec CyFlow miniPOC *Market launched; is higher throughput than the other POC CD4 tests; measures CD4 count, CD4 % and total lymphocyte count; flow cytometry-based*	**$3.15**

[1] Incoterms for prices are EXW or FCA

Continued overleaf

The Product Guide Findings – In Brief continued

POINT-OF-CARE HIV AND HCV VIROLOGICAL TESTS

For EID, there are three POC and near-POC technologies currently available in the market and one in the pipeline, with prices ranging from $6.50-37.40 per test.

- The Alere Q is a true POC dedicated for EID testing with prices ranging from $15-25 per test depending on volume.
- The Cepheid HIV-1 Qualitative assay is a near-POC system. Prices range from $13-18 per test, depending on volume.
- Diagnostics for the Real World (DRW) offers semi-POC (SAMBA I) and true POC (SAMBA II) tests, with prices ranging from $18-37 per test, depending on volume.
- The LYNX p24 (Northwestern Global Health Foundation) is a qualitative p24 antigen based immunochromatographic assay in the pipeline. Volume-based pricing ranges from $6.50-$15 per test.

There are three HIV viral load technologies currently available in the market and two in the pipeline. Prices span from $12-37.40 per test.

- The Cepheid HIV-1 Quantitative assay is a near-POC system. Prices range from $12-17 per test, depending on volume.
- Diagnostics for the Real World (DRW) offers semi-POC (SAMBA I) and true POC (SAMBA II) tests, with prices ranging from $18-$37 per test, based on volume.
- The truelab/truenat HIV assay (Molbio Diagnostics) is a true POC system currently in the pipeline. Test price will be around $20.
- The Savanna Quantitative RealTime HIV-1 assay (Quidel Corporation) is a near-POC system. Test price is expected to be around $11.

There is only one near-POC technology commercially available for HCV virological testing, the Xpert HCV Viral Load (Cepheid). The company offers volume-based pricing from $12-17 per test. Products in the pipeline include:

- Truelab/truenat HCV Viral Load (Molbio Diagnostics) is a true POC assay. The test price is expected to be approximately $20.
- The Genedrive HCV ID Test Kit is undergoing CE-marking; launch is expected in Q3 2017. Prices will range from $25-30.

Further technical information on pipeline tests may be found in the HIV/AIDS Diagnostic Technology Landscape, published by UNITAID.[14]

TABLE 3:

POINT-OF-CARE HIV AND HCV VIROLOGICAL TESTS	COST PER TEST IN USD[1]
Alere q HIV 1/2 Detect (EID) *Market launched and quality assured, fully decentralisable; cartridge-based*	**$15 - 25**
Cepheid Xpert HIV-1 qual (EID), Xpert HIV-1 Viral Load and Xpert HCV Viral Load *Market launched and quality assured; GeneXpert is modular and near POC, but not fully decentralisable; cartridge-based*	**$13 - 18**
Diagnostics for the Real World SAMBA HIV-1 Qual Test, SAMBA II HIV-1 Qual Whole Blood Test, SAMBA HIV-1 Semi Q Test and SAMBA II HIV-1 Semi Q Plasma Test *Semi-quantitative test for viral load at the 1,000 copies/mL virological failure threshold, SAMBA II is more decentralisable than SAMBA, is fully automated and has random access but has a lower throughput; SAMBA operates by batch testing and requires additional pipetting steps compared to SAMBA II; cartridge-based*	**$18 - 37**
Genedrive HCV ID Kit (viral load) *Currently under CE-marking, to be launched in Q3 2017; POC but not fully decentralisable as the test only accepts plasma and requires manual steps to perform the test*	**$25 - 35**
Molbio Diagnostics Truenat HIV and Truenat HCV (viral load) *Not yet market launched; may be launched in India first; the company has developed a cartridge-based, fully automated POC*	**$15 - 20**
NWGHF LYNX HIV p24 Antigen Test *Not yet market launched; non-molecular test; simple, affordable and fully decentralisable; cartridge-based*	**$6.50 - 15**
Quidel Savanna Quantitative RealTime HIV-1 Assay *Not yet market launched; 50µL plasma (capillary whole blood separated by plasma separator) and 200µL plasma options; cartridge-based*	**$11**

[1] Incoterms for prices are EXW or FCA

LABORATORY-BASED HIV AND HCV VIROLOGICAL TESTS

Only commercially available products were included in this report.

- There are three dedicated early infant HIV diagnostic tests, from Abbott, Biocentric and Roche, all priced at a range of $13 – 22.50 per test.
- Many more tests exist for HIV viral load, including from Abbott, Biocentric, bioMérieux, Cavidi, Hologic, Qiagen, Roche, Sacace and Siemens. Prices were reasonably competitive, with all companies except Siemens offering prices below $25 per test.
- Roche offers the lowest price at $9.40 per test, and Siemens the highest at $54-72 per test.
- Only bioMérieux has a WHO-prequalified product for using DBS samples for viral load testing, although Abbott, Roche, among others, are working on improved DBS solutions that will hopefully be approved in the near future.

Using existing molecular platforms for HCV testing will facilitate DAA scale-up.

- Abbott, Biocentric, Qiagen, Roche, Sacace and Siemens have HCV RNA test kits that can be run on the same platform as HIV testing.
- Abbott, Roche and Sacace offer real time PCR-based HCV genotyping (GT) kits (all but the Roche kit can be run on the same platform as HIV).

Prices for HCV viral load and genotyping are currently higher than for HIV, ranging from $13-100 per RNA test, and from $13-350 per genotype test. (See Table 4) As market demand increases volumes and competition in developing countries, pricing for RNA testing should hopefully drop to similar levels as for HIV, and, when pan-genotypic HCV regimens are rolled out, it will no longer be necessary to perform pre-treatment genotyping. Considering that similar technologies are employed, there is no reason for cost of goods to differ between HIV and HCV. Countries and donors should negotiate bundled pricing (where multiple tests are purchased from the same supplier for use on the same instrument), and opt for reagent rental contracts rather than purchasing instruments upfront. If instruments are purchased, comprehensive service and maintenance contracts should be negotiated for the length of instrument use.

The only fully automated instrument for core antigen (cAg) testing is the Abbott ARCHITECT HCV core antigen, at $25-30 per test. The ARCHITECT platform has a wide screening menu, so it may be interesting for countries as a general, high- volume, high-throughput, laboratory-based tool for screening multiple analytes.

TABLE 4:

LABORATORY-BASED HIV AND HCV VIROLOGICAL TESTS	COST PER TEST IN USD[1]
Abbott ARCHITECT HCV Ag *The only fully automated, highly sensitive, commercially available, quality approved, HCV core antigen test; chemiluminiscent microparticle immunoassay*	**cAg: $25 - 50**
Abbott RealTime HIV-1 Qualitative (EID), RealTime HIV-1 (viral load) and RealTime HCV (viral load) and RealTime HCV Genotype II *Fully polyvalent single m2000 platform for HIV EID and viral load, as well as HCV viral load and genotyping; different throughput options (m24sp and m2000sp); RNA specific for HIV viral load*	**HIV: $11 – 23** **HCV: $11 – 23**
Biocentric Generic HIV DNA Cell (EID), Generic HIV Charge Virale and Generic HCV Charge Virale *Open platform for HIV and HCV; platform has a small footprint; allows for low instrument and test prices without the need for high volumes to bring costs down*	**EID: $13** **HIV: $15** **HCV: $23**
bioMérieux NucliSENS EasyQ HIV-1 *Only platform that has received regulatory approval to use DBS as a sample type for HIV viral load*	**HIV: $23**
Cavidi ExaVir Load *Non-molecular platform and therefore not affected by amplicon contamination; not as dependent on precision pipetting; not automated and very hands-on; medium throughput; can only be used with plasma*	**HIV: $12 - 25**
Hologic Aptima HIV-1 Quant Dx Assay and Aptima HCV Quant Dx Assay *New automated platform for HIV and HCV; awaiting market launch of HCV test*	**HIV: $10 – 25** **HCV: $10 - 25**
Qiagen artus HI Virus-1 RG RT-PCR, artus HI Virus-1 QS-RGQ, artus HCV RG RT-PCR and artus HCV QS-RGQ (viral load) *Different options available for HIV and HCV viral load testing; platform not widely used in low-resource settings*	**HIV: $16 – 45** **HCV: $16 – 45**
Roche CAP/CTM HIV-1 Qualitative (EID), CAP/CTM HIV-1 (viral load), CAP/CTM HCV Qualitative and CAP/CTM HCV (viral load) *Different throughput options (Taqman 48 and Taqman 96); current extraction method extracts DNA and RNA but HIV viral load is currently being optimised on DBS using the "Free Virus Elution" protocol, which is RNA-specific*	**EID: $9.40** **HIV: $9.40** **HCV: $35 - 45** **HCV GT: $35**
Sacace HIV Real-TM Quant Dx, HCV Real-TM Quant Dx and HCV Genotype Plus Real-TM *Open platform for HIV and HCV; platform has a small footprint; allows for low instrument and test prices without the need for high volumes to bring costs down*	**HIV: >$20** **HCV: >$20**
Siemens VERSANT HIV-1 RNA Assay, VERSANT HCV RNA Assay (viral load) and VERSANT HCV Genotype 2.0 Assay *Widely used for HCV viral load and genotyping, but not widely found in low-resource settings; expensive*	**HIV: $54 – 72** **HCV: $72 – 100** **GT: $132 – 350**

[1] Incoterms for prices are EXW or FCA

QUALITY ASSURANCE

This report is a pricing guide and, apart from indicating whether the product has received regulatory approval, does not include detailed information about the quality of the products listed. However, since quality is an important factor in procurement decisions, this section provides a brief overview of the key entities that provide quality assessments of diagnostic tools.

1. WHO PREQUALIFICATION

The WHO List of Prequalified Diagnostic Products, commonly known as WHO Prequalification, was initiated by WHO and developed in collaboration with other UN organisations, principally for procurement by UN agencies. The project evaluates diagnostic and monitoring test manufacturers according to WHO-recommended standards of quality and compliance with Good Manufacturing Practices.[15]

The WHO Prequalification Programme is a benchmark for the identification of quality diagnostics for HIV, malaria and hepatitis B and C, and includes both a laboratory evaluation (to assess the operational and performance characteristics) and site inspection (to assess manufacturing quality). However, the programme is still is its infancy relative to medicines prequalification and, as such, many products have yet to be prequalified.

A key success factor to the WHO Prequalification Programme is that financial support to national programmes is dependent on purchasing medicines and diagnostics that meet clear quality assurance criteria. The WHO Prequalification Programme has played an important role in providing guidance to purchasers on the quality of diagnostics, thereby creating a positive market dynamic where manufacturers strive to reach WHO standards in order to comply with procurement policies.

WHO recognises the evaluation of products by regulatory authorities that apply stringent standards for quality similar to those recommended by WHO, such as the US Food and Drug Administration (US FDA), and the European Economic Area conformity mark (CE mark). However, in order to comply with the standards set by WHO, which may be more suited to resource-limited areas, further information may be required from manufacturers.

It is important that manufacturers approach WHO for guidance before submitting a dossier.

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2. US FOOD AND DRUG ADMINISTRATION

The US FDA is a public organisation offering strict regulatory approval for medical devices, including in vitro diagnostics.[16] Approval based on a pre-market notification (510K) may be issued for products only needing to demonstrate substantial equivalence to an already-approved product, whereas, for Class III (the highest-risk category) medical devices, a more stringent pre-market approval is required.

3. EUROPEAN CONFORMITY

European standards for medical devices are based on the European Council Directive 93/42/EEC for CE marking.[17] Under this directive, private notified bodies in each country are responsible for the CE marking of medical devices, with stringency based on a Class system – Class A (the highest-risk category) requires the most stringency. Products submitted under low-risk categories (such as tests for tropical diseases, tuberculosis and CD4) only require a self-declaration for certification, and are therefore not well scrutinised. However, new more stringent regulations on CE-marking will come into force in 2017, this will result in more medical devices and in-vitro diagnostics requiring assessment by notified bodies; this will include products in the low-risk category as well as products intended for research-use-only.[18]

4. INTERNATIONAL MEDICAL DEVICE REGULATORS FORUM

The International Medical Device Regulators Forum (IMDRF) was founded in February 2011, replacing the Global Harmonisation Task Force. It is composed of a voluntary group of medical device regulators from countries around the world with the aim of accelerating harmonisation and convergence.[19]

5. ISO CERTIFICATION

ISO International Standards are a benchmark for safety, reliability and quality. The ISO13485:2003 standard, used to assess the manufacturing quality of medical devices, may be used to assess the quality of the management system for production.[20] It is usually one of the requirements to gain approval from a strict regulatory authority (unless the SRA has its own parallel system).

6. DONOR PROCUREMENT POLICIES

The Global Fund to Fight AIDS, Tuberculosis and Malaria and UNITAID have a quality assurance policy for the procurement of diagnostic products that became effective in March 2011, and has been recently updated to include new products recommended by WHO.[21] As the WHO list of diagnostic products is limited, countries may procure other products as long as a regulatory authority member belonging to the IMDRF authorises them for use.

In addition, the Expert Review Panel for Diagnostics (ERPD) was established in 2014 to provide guidance on the purchase of products that are still in the process of obtaining regulatory approval but are urgently required for patient benefit in countries. The ERPD is intended as a time-limited stop-gap measure to facilitate market entry of new products into countries without unnecessary delay, and is modelled on the successful Expert Review Panel for Medicines.[22] Based on a risk-benefit analysis, ERPD classifies products into four categories: products falling into Risk Categories 1 and 2 may be considered for time-limited procurement; products falling into Risk Category 3 may be considered for time-limited procurement only if there is no other option and the benefit of diagnosing and/or making treatment decisions is higher than the risk of using the product; and products falling into Risk Category 4 may not be procured under any circumstances. Both HIV and HCV tests are considered by the ERPD and there have been three invitations for product applications so far.

7. POST-MARKET SURVEILLANCE

It is important to note that authorisation by a strict regulatory body is only a starting point. It is critical that continuous post-market surveillance on the performance and quality of the product, as used as intended, and on the population of interest be captured so that any problems may be reported to the relevant authorities and promptly addressed.[23]

METHODOLOGY

This report includes technical and price information for all known commercially available, or soon to be available, point-of-care CD4, and POC and laboratory-based HIV and HCV virological, tests.

Data was collected between April and June 2017. All companies known to be developing and producing the included technologies were contacted and asked to fill in a standard questionnaire on product and pricing information. Some companies did not respond, while other products were not yet ready for inclusion in this report, as they are still too early in the development pipeline.

Some important preliminary remarks on the data presented in this report:

- This report provides information on the prices of products. It does not include costs linked to equipment shipping, standing laboratory, staff, sample transport, external quality control, maintenance or other overhead expenses.
- The manufacturers provided the prices listed in this publication. These are indicative prices only, therefore the actual costs paid for these items may be higher or lower, depending on specific contexts.
- Companies use different trade terms (known as incoterms).* These trade terms outline the responsibilities of the manufacturer and purchaser with regards to transport, international freight and insurance costs. In order to provide comparable pricing, companies were asked to provide pricing information using FCA (free carrier pricing).
- In general, the price per test calculation consists of the total price of reagents, buffers, and controls needed per test result. It does not factor in the price of instrumentation, consumables required but not supplied by the manufacturer, infrastructure or labour.

* For more information on incoterms, please refer to the Glossary.

HOW TO READ THE PRODUCT TABLES

1. GENERAL INFORMATION

HIV diagnostic companies were asked to provide information on the technical specifications of their products; pricing information; volume-based and tiered pricing; maintenance, training and warranty information; and contact information. The majority of information requested was provided and all information that was received is included in this report. Only company-provided information was included. The narrative provides a brief comparison of the products.

All prices are quoted in US Dollars (US$). When currency was converted from Euro (€) to (US$) a currency exchange rate of 1 to $1.12 was used, as per currency exchange on 3 June 2017.

Performance information was requested but, in most cases, companies derived from it only from the product insert, and end-users should therefore perform a more comprehensive investigation of performance. In particular, independent and peer-reviewed literature will be important to gauge the true performance in real world settings.

2. TECHNICAL SPECIFICATIONS

Technological set-up refers to the type of assay (either laboratory or POC, which can also be near-POC), instrument compatibility with other brands, and the extent to which processes are automated or manual. The mean time between failures refers to the elapsed time between inherent failures of a system during operations.

Polyvalency refers to the platform's capability to be used for multiple disease assays, or measurement of other analytes.

3. PRICING INFORMATION

When applicable, pricing for diagnostics assays were divided into categories: whether consumables, instruments, or required materials are or are not provided by the company. When applicable, sample extraction and preparation items were separated from items required for amplification and detection. If manual or automated options are available, both were included.

The sample throughput capacity, and therefore the number or size of the instruments required, will vary depending on the laboratory and context. Therefore, the number of samples per run and run times for instruments are provided, when available. Prices are displayed according to the incoterm* provided by the company.

The price per test is the sum cost of reagents and controls per test result. When manual or automated options exist, these costs per tests are differentiated. When companies provided cost per test result in a different manner, the components of these test results are specified. FCA prices were requested.

4. VOLUME-BASED AND TIERED PRICING

Companies were asked to provide details on their volume-based and/or tiered pricing schemes, although this was rarely provided. Some companies have preferential pricing for high disease burden and/or developing or low-income countries. Some companies requested that interested parties contact them directly for more information on possible volume-based or tiered pricing.

5. MAINTENANCE, TRAINING AND WARRANTY INFORMATION

The details and pricing information provided by manufacturers has been incorporated into the maintenance, training, and warranty tables. Unfortunately, most manufacturers do not offer reagent rental plans (RAP). It is unclear why, but is likely due to unreliable volume forecasts from end-users or too few volumes to make a RAP contract affordable to the supplier.

6. CONTACT INFORMATION

Contact information is given to enable interested parties to contact the companies directly for more detailed pricing and other information, and to place orders.

* For more information on incoterms, please refer to the Glossary.

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POINT-OF-CARE CD4
ALERE

01 | TECHNICAL AND PERFORMANCE INFORMATION

Company	ALERE		Product	PIMA ANALYSER	
ASSAY		**INSTRUMENT**		**KIT**	
Intended use (as per regulatory approval)	CD4 testing	**Size of device**	23 cm x 13 cm x 16 cm	**Kit components**	Only the instrument and the CD4 cartridge are required. Optional accessories are available (see pricing table).
Principle of the assay	Fixed volume cytometry	**Weight of device**	2.54 kg	**Kit sizes**	25 & 100
Type of result	Quantitative	**Robustness**	Very robust & portable	**Internal control(s)**	Yes
Dynamic range	3 - 2,168 cells/µL	**Environmental requirements**	Temperature: 10 - 40°C Humidity: 10 - 95% Altitude: 0 - 2,000m	**Compatible with EQA and which?**	Yes, QUASI, UK NEQAS, AFRIQAS, LYMPHOSURE, STRECK, etc.
Output	CD4 count in cells/µL	**Power requirements**	100 - 240 V at 47 - 63 Hz	**Mean time between failures**	Not provided
T-cell specific?	Yes	**Time to battery charge**	Recommendation overnight	**Transport and storage**	Room temperature
Polyvalency	In development	**Battery duration (hours)**	8 hours (when battery is new)	**Fridge at -80°C required?**	No
PERFORMANCE		**Alternative charging options**	Solar & car charger	**Shelf life (of each item in the kit)**	12 months
Accuracy (source)	See package insert (V&V studies)	**Ease of use**	Keypad on the device & optional USB printer	**Performance protocol (steps)**	Collect sample in the cartridge and run the test
Bias - CD4 counts, adults (source)	-10 cells (21 - 3) / µL (V&V studies)	**Display languages**	English & simplified Chinese	**Non-proprietary components required outside of the kit**	No, fingerstick kit and printer paper are optional
Bias - CD4 counts & %, children (source)	-10 cells (21 - 3) / µL (V&V studies)	**Built-in memory storage capacity**	1,000 tests	**Regulatory approval**	CE-IVD, WHO PQ
Within run precision, counts & % (source)	11.6% (7 - 16.6%) (V&V studies)	**Connectivity options**	Yes, USB cellular modem with datapoint connectivity solution	**In-country approvals**	Most countries in the developed world; contact local representative
SAMPLE		**Interpretation of result**	No	**USAGE**	
Sample preparation	None	**Instrument lifespan**	Alere guarantee 10 years	**Technical skill required**	No
Sample type	WB capillary & venous WB from EDTA Vacutainer	**Other non-proprietary equipment required**	No	**Applicable settings**	Point-of-care & small labs
Sample volume	25µL	**Regulatory approval**	CE-IVD, WHO PQ	**Laboratory set-up**	No
Sample stability	48 hours in an EDTA Vacutainer			**Waste disposal requirements**	Standard biohazard waste disposal
Time to result	18 - 20 minutes				
Capacity	1 test at a time				
Batching?	No				
Throughput per end-user per hour and/or 8hr day	24 tests				

Continued overleaf

Point-of-Care CD4 – Alere continued

02 | PRICING

Prices quoted to MSF for 2015. Please consider pricing indicative only.

Instrument		Reference number	FCA ($)
Pima Analyser	1 Pima Analyser device	260300003	$5,500
	1 power transformer		
	1 EU power cable		
	1 Pima Analyser User Guide		
	1 Pima bead standard (260400011)		
Pima Instrument & Accessory Pack	1 Pima Analyser	260300004	$6,050
	1 Power transformer		
	1 EU cable		
	1 Pima Analyser User Guide		
	1 Pima Bead standard (260400011)		
	1 Pima Bag (260400001)		
	1 Pima Printer (260400007)		
	1 Connectivity Pack (260400015)		

Cartridge/reagents		Reference number	FCA ($)
Pima CD4 100X cartridge kit	100 Pima CD4 foil sealed test cartridges with 1 product insert	260100100	$595
Pima CD4 2 5X cartridge kit	25 Pima CD4 foil sealed test cartridges with 1 product insert	260100025	
Fingerprick Sample Collection Kit for 100 Pima CD4 tests	4 units of safety lancets (x28)	260400199	$80
	4 units of gauze swabs (x25)		
	1 unit of alcoholic swabs (x100)		
	4 units of plasters (x26)		
	1 safety-lancet user guide		
Pima Printer Paper I	10 rolls thermal paper, non-adhesive	260400009	$32
Pima Printer Paper 2	10 rolls thermal paper, adhesive	260400010	$180
Pima Bead Std	1 normal cartridge	260400011	$50
	1 low cartridge		
	1 Pima bead standard user guide		

Instrument Accessories		Reference number	FCA ($)
Pima Instrument Bag	1 Pima Analyser bag	260400001	$180
Pima Printer	1 Pima Printer	260400007	$350
	1 Pima Printer User Guide		
	1 Roll thermal paper 1, coated, non-adhesive		
Pima Connectivity Pack 1	1 Pima Connectivity Pack	260400015	$550
	1 User Manual		
Alere Solar Solution	1 Solar Panel	260400040	$1,750
	1 Power Pack (260400015)		
	1 User Manual		
Alere Power Pack	1 Power Pack	260400017	$1,150
	1 User Manual		

Non-proprietary equipment and consumables	Reference number	FCA ($)
None		

Cost per device	$6,000 – $12,000	Cost per test result	$6 – $12

03 | TIERED AND VOLUME-BASED PRICING

No Information Provided

04 | MAINTENANCE, WARRANTY & TRAINING

	Description
Maintenance (including instrument swap)	The instrument does not require any preventative maintenance.
Length(s) of warranty and additional costs for extended warranty/care plan	Alere offer a 2 year warranty. Customers can negotiate an extended warranty and several options are available.

05 | CONTACT INFO

Rozanne Tzuk
Alere, 1 Dan Street
North Industrial Area, POB 360, Yayne
70650, Israel

Website: www.alere.com
Tel: +972 - 8 - 942 - 9201 (ext. 206)
Email: rosanne.tzuk@alere.com

POINT-OF-CARE CD4
BD

01 | TECHNICAL AND PERFORMANCE INFORMATION

Company	BD INTERNATIONAL, BECTON, DICKINSON AND COMPANY	Product	BD FACSPRESTO
ASSAY		**PERFORMANCE**	
Intended use (as per regulatory approval)	Automated system for in vitro diagnostic use in performing the direct enumeration of CD4 absolute count, CD4 percentage of lymphocytes, and haemoglobin concentration.	**Intra-assay precision, counts & % (source)**	CD4 absolute count CV: - 2.59% for 927 cells/µL - 5.78% for 155 cells/µL %CD4 CV - 1.53% for 44% CD4 and SD of 0.73 for 13% CD4 Hb CV - 1.09% for 13 g/dL - 2.26% for 7 g/dL (Clinical trial data)
Principle of the assay	3-colour Imaging cytometry with fluorescent labeled antibodies to count CD4 and %CD4 in whole blood. Imaging for absorbance for total haemoglobin.	**Intra-assay precision, counts & % (source)**	CD4 absolute count CV - 3.30% for 962 cells/µL - 6.79% for 112 cells/µL %CD4 CV - 1.74% for 44% CD4 and SD of 0.75 for 13% CD4 - Hb CV - 1.14% for 17 g/dL - 1.52% for 13 g/dL - 2.42% for 7 g/dL (Clinical trial data)
Type of result	(1) Absolute CD4 count (CD4 lymphocytes/µL) (2) %CD4 (CD4 percent of total lymphocytes) (3) Hb (g/dL)	**SAMPLE**	
Linear range	Validated range: (1) CD4 absolute counting: 50 - 4,000 cells/µL (2) %CD4: 5 - 60% (3) Hb concentration: 2 - 20g/dL	**Sample preparation (steps)**	None
Output	(1) Absolute CD4 count (CD4 lymphocytes/µL) (2) %CD4 (CD4 percent of total lymphocytes) (3) Hb (g/dL)	**Sample type**	Capillary and venous whole blood.
T-cell specific?	Yes: The assay identifies CD4 positive lymphocytes within a population of total lymphocytes (including T, B, and NK cells) identifed by CD3 and/or CD45RA. CD14 expressing cells (monocytes) are excluded.	**Sample volume**	<30µL
Polyvalency	No (current product is already a multiplexed assay for CD4 absolute count, %CD4, and Hb in a single cartridge).	**Sample stability**	2 hours (sample loaded in cartridge); 24 hours (venous EDTA blood not loaded in cartridge)
PERFORMANCE		**Time to result**	22 minutes for first sample; thereafter 4 minutes per sample for batched samples.
Accuracy (source)	For the CD4 or %CD4 assay using venous or capillary whole blood: correlation with gold standard FACSCalibur shows R^2 ≥0.96 and deming slope ranging from 0.97 to 1.03; For Hb from venous samples, correlation with gold standard Sysmex shows R^2 ≥0.96 and deming slope of 0.94. (Clinical trial data from Kenya)	**Capacity**	10 samples/hour
		Batching?	Yes, 10+ samples.
		Throughput per end-user per hour and/or 8hr day	80 samples per operator per day.
Bias - CD4 counts, adults (source)	%Bias compared to gold standard FACSCalibur: - CD4 count: venous -0.28%, capillary 7.1% - %CD4: venous 3.6%, capillary 0.7% for capillary %Bias for Hb compared to gold standard Sysmex - Venous -3.04%, capillary -1.14% (Clinical trial data from Kenya)		
Bias - CD4 counts & %, children (source)	Separate analysis for children was not conducted.		

Continued overleaf

Point-of-Care CD4 – BD continued

INSTRUMENT		KIT	
Size of device	W 25.9 x H 28.5 x D 25.1 cm	**Kit components**	BD FACSPresto Cartridge Kit: - Cartridges for 100 tests - Finger Stick Sample collection kit (100) - 100 BD Lancets - 100 alcohol swabs - 100 cotton gauzes - 100 band-aids - 100 transfer pipettes
Weight of device	7 kg	**Kit sizes**	100 tests
Robustness	Robust: designed for resource limited settings (no maintenance required, no internal cleaning required, only outside cleaning as needed).	**Internal control(s)**	Yes, embedded in cartridge
Environmental requirements	Operating temperature: 10 - 40°C Humidity: 10 - 95%	**Compatible with EQA and which?**	UKNEQAS (Also compatible with BD Multicheck Controls)
Power requirements	Built in battery. 100 - 240V, 50 - 60Hz.	**Mean time between failures**	<5% failure in 12,000 test cycles
Time to battery charge	Overnight charge (8 hours).	**Transport and storage (include temperature)**	Shipping temperature: 45 - 60°C; shipping humidity: 10 - 95% (5 days) Storage temperature: 4 - 31°C; storage humidity: 10 - 95%
Battery duration (hours)	6 Hours when fully charged.	**Fridge at -80°C required?**	No
Alternative charging options	Solar Charger kit and external back-up battery.	**Shelf life (of each item in the kit)**	12 months
Ease of use	- Large colour touchscreen display. - Home screen with intuitive menu for incubation timer, sample run, results, QC and help. - On-board 10 timers to manage incubation for up to 10 samples at the same time. - Running sample menu allows for patient ID input, operator selection and running the sample inside instrument by opening the cartridge inlet door. - Result will be displayed and printed automatically. - All errors and malfunction of system will be displayed. - Status of battery charging will be actively displayed on the screen all the time. - In QC mode, on demand instrument QC can be run. - In QC mode, process controls and EQA samples can be run. - Results menu will allow data filtration for printing and export via USB port. - Help menu offers on-board video for entire workflow from sample collection to result exporting.	**Performance protocol (steps)**	(1) Collect sample, (2) incubate, (3) run test and read result.
		Non-proprietary components required outside of the kit	None
		Regulatory approval	CE-Marked (IVD 98/79/EC) and WHO Prequalified
		In-country approvals	Yes, in most countries, where CE Mark is accepted.
		USAGE	
		Technical skill required	Medium to low skill lab technician or health care worker.
		Applicable settings	Resource-limited settings, health centre, PMTCT centre, HIV clinic.
		Laboratory set-up	No installation required.
		Waste disposal requirements	Dispose cartridge in biohazard waste disposal container.
Display languages	N/A (pictograms and numbers are displayed).		
Built-in memory storage capacity	Data for 12,000 patient results.		
Connectivity options	Direct connectivity option currently not available. USB can be used to export data.		
Interpretation of result	No		
Instrument lifespan	5 years		
Other non-proprietary equipment required	None (on-board mini printer is part of the instrument).		
Regulatory approval	CE-Marked (IVD 98/79/EC) and WHO Prequalified		

02 | PRICING

Instrument		Reference number	FCA ($)	Cartridge/reagents		Reference number	FCA ($)
BD FACSPresto	Near Patient CD4 Counter	651000	<$10,000	BD FACSPresto Cartridge Kit	Cartridges for 100 tests, finger stick sample collection kit, 100 BD lancets, 100 alcohol swabs, 100 cotton gauzes, 100 band-aids, 100 transfer pipettes.	655495	~$1,000
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
BD FACSPresto Solar charger kit	1x Solar panel 1x Solar generator 1x Power supply 1 x Instructions for Use in English, French, Spanish	658212	<$1,500				
BD FACSPresto Car battery charger adaptor	1x 12 VDC power adaptor with car cigarette lighter plug 1 x Instructions for Use in English, French, Spanish	658860	<$400				
BD FACSPresto Power Generator (rechargeable power battery)	1x 8mm Power supply 1 x Instructions for Use in English, French, Spanish	658885	<$600				
BD FACSPresto printer paper	1x 10 rolls: sufficient for printing 1,200 test results	655038	<$50				
Cost per device			**~$10,000**	**Cost per test result**			**<$10**

Intellectual property		
Patent number / application number / PCT number	Title	Legal Status
US7738094 PCT/US2008/050241	Method, system, and compositions for cell counting and analysis	Granted
US8248597 PCT/US2008/052041	Method, system, and compositions for cell counting and analysis	Granted
US14/537,769 PCT/US2014/064873	Microimager Analysis System Comprising Optics, and QC for Analysis of Microcartridge Data	Pending
US9097640 PCT/US2008/052041	Method, System, and Compositions for Cell Counting and Analysis	Granted
US14/533,949 PCT/US2014/064159	Porous Solid Frit Comprising Reagent for Passive Mixing	Pending
US14/152,954 PCT/US2014/011163	Means for enabling capillary flow within a sealed microfluidic device	Pending
US7816135	Method of Analyzing Lymphocytes	Granted
US9523682	Methods and Systems for Detecting an Analyte in a Sample	Granted

03 | TIERED AND VOLUME-BASED PRICING

No Information Provided

Continued overleaf

Point-of-Care CD4 – BD continued

04 | MAINTENANCE, WARRANTY & TRAINING

	Description
Leasing or reagent rental	Reagent rental programme available. Please inquire.
Installation	No installation required.
Training	In-country 2-day Good Start Program (GSP) training will be provided. Training can be conducted in English or French. On site training can be arranged if requested and will be conducted by the local team. Training tools will be available and provided. Proficiency testing will be conducted after training. Training materials will be provided including SOPs and Quick Reference Guides. Web links to training materials may be available in some regions.
Maintenance	No maintenance required. All inclusive warranty for 3 years, including instrument swap.
Length(s) of warranty and additional costs for extended warranty / care plan	3 Years all inclusive. Warranty extension available for additional 2 years for a fixed price.
Warranty components	- All inclusive in warranty. - No preventive maintenance required. - Instrument performs self-check each time it is turned on. - No calibration required (factory calibrated). - Internal self calibration performed as needed. - Warranty includes replacement of units. - No internal cleaning required. - No on site repair needed. - Instrument will be swapped by local depot centre. - Local dedicated POC coordinator will manage logistics and any issues related to instrument performance. - All parts are fully tested and reliable for the warranty period.
Turnkey option	No (no installation required).
In-country / regional technical support availability	- In-country technical support team and depot centre available for repair and swap. - In addition, in-country POC coordinator available to coordinate and support all BD FACSPresto activities, including logistics, order placement and swaps.

05 | CONTACT INFO

Henok Tilahun
BD, WW Marketing Manager

2350 Qume Drive
San Jose California USA

Website: www.bd.com
Tel: +1-408-954-2436
Mobile: +1-408-221-1448
Email: henok_tilahun@bd.com

POINT-OF-CARE CD4 MILLIPORE

01 | TECHNICAL AND PERFORMANCE INFORMATION

Company	EMD MILLIPORE (MERCK MILLIPORE)	Product	MUSE AUTO CD4/CD4% SYSTEM
ASSAY		**INSTRUMENT**	
Intended use (as per regulatory approval)	Enumeration of CD4 absolute count and CD4 percentage of lymphocytes.	**Size of device**	H 22 x W 20 x D 28 cm
Principle of the assay	Flow Cytometry, green laser, forward scatter, two colour fluorescence.	**Weight of device**	4kg
Type of result	Quantitative	**Robustness**	TBD after testing in Cameroon.
Linear range	TBD	**Environmental requirements**	Temperature: 16 - 35 °C
Output	CD4 count and percentage	**Power requirements**	100 - 200 VAC, 50/60 Hz, 80 W, 15 VDC, 5A
T-cell specific?	Yes	**Time to battery charge**	TBD
Polyvalency	Not at this time	**Battery duration (hours)**	TBD
PERFORMANCE		**Alternative charging options**	External battery in development.
Accuracy (source)	Clinical study in process.	**Ease of use**	5 USB ports available. Data station on board. Touch screen. Histograms and Scatterplots displayed. No printer included, printer must be Microsoft 7 compatible.
Bias - CD4 counts, adults (source)			
Bias - CD4 counts & %, children (source)			
Intra-assay precision, counts & % (source)		**Display languages**	English
Inter-assay precision, counts & % (source)		**Built-in memory storage capacity**	Unlimited, Dell computer.
SAMPLE		**Connectivity options**	5 USB ports for accessories or for interface.
Sample preparation	Two steps, no wash, 30 minutes.		
Sample type	Venous blood.	**Interpretation of result**	Auto acquisition; automated and manual gating.
Sample volume	10µL	**Instrument lifespan**	10 years
Sample stability	48 hours	**Other non-proprietary equipment required**	Pipettes, vortex.
Time to result	4 minutes	**Regulatory approval**	Not applied for yet as clinical study is still in process.
Capacity	15 tests per hour		
Batching?	Yes		
Throughput per end-user per hour and/or 8hr day	15 Samples per hour / 120 per day, not including sample prep time		

KIT	
Kit components	Reagent cocktail, cell lyses.
Kit sizes	100, 500 and 1000 test kits.
Internal control(s)	Not provided.
Compatible with EQA and which?	TBD
Mean time between failures	TBD
Transport and storage	2 - 8 °C
Fridge at -80°C required?	No
Shelf life (of each item in the kit)	12 months
Performance protocol (steps)	Two steps, no wash protocol.
Non-proprietary components required outside of the kit	None
Regulatory approval	Not applied for yet as clinical study is still in process.
In-country approvals	Not applied for yet as clinical study is still in process.
USAGE	
Technical skill required	HS Diploma.
Applicable settings	Small hospital or clinic laboratory.
Laboratory set-up	Hospital lab, clinic lab, ambulatory care lab.
Waste disposal requirements	Liquid waste is bleached.

Continued overleaf

Point-of-Care CD4 – Millipore continued

02 | PRICING

Instrument		Reference number	FCA ($)	Cartridge/reagents		Reference number	FCA ($)
Muse Auto CD4/ CD4% system	Not yet available for sale; pending regulatory release.	0500-3115	$17,783 (€16,000)	Not yet available for sale; pending regulatory release.			
				Muse Auto CD4/CD4% reagent kit	100 test kit	MCA100101	$445 (€400)
				Muse Auto CD4/CD4% reagent kit	500 test kit	MCA500101	$2,223 (€2,000)
				Muse Auto CD4/CD4% reagent kit	1,000 test kit	MCA1XK101	$4,445 (€4,000)
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
UPS	Product in development			These products are in development: Pipettes Pipette tips (disposable, bio-degradable) Sample tubes (disposable, biodegradable)			
Alternate Battery Pack	Release data: Q1 2016						
Cost per device			**~$18,000**	**Cost per test result**			**~$5**

03 | TIERED AND VOLUME-BASED PRICING

No Information Provided

04 | MAINTENANCE, WARRANTY & TRAINING

	Description
Leasing or reagent rental (RAP)	Not provided.
Installation	Not provided.
Training	(1) Training is on site and takes 1-2 days. (2) An operator's manual, package insert, material data safety sheet and product brochure will be available in English, French and Portuguese. (3) Proficiency testing will be available through a third party. (4) A training website for the product is in development.
Maintenance (including instrument swap)	Distributors will handle servicing the instruments.
Length(s) of warranty and additional costs for extended warranty / care plan	One year warranty.
Warranty components	All parts and service.
Turnkey option	Not provided.
In-country / regional technical support availability	Through distributor and at Merck regional offices.

05 | CONTACT INFO

Jim Mulry
Clinical Development Manager, EMD

EMD Millipore, a division of Merck, KGaA, Darmstadt, Germany,

25801 Industrial Blvd., Hayward, CA 94545, USA

Website: www.emdmillipore.com
Tel: +15104274641
Email: jim.mulry@emdmillipore.com

POINT-OF-CARE CD4 OMEGA DIAGNOSTICS

01 | TECHNICAL AND PERFORMANCE INFORMATION

Company	OMEGA DIAGNOSTICS	Product	VISITECT CD4
ASSAY		**SAMPLE**	
Intended use (as per regulatory approval)	Estimation of CD4+ T-cell count to be used as an aid to initiation in the treatment of HIV infection and management of patients in the advanced stages on HIV.	**Sample preparation (steps)**	None
Principle of the assay	Rapid immunochromatographic assay for the estimation of full-length CD4 protein associated with CD4+ T-cells in human whole blood. A capture monoclonal antibody (MAb) specific for the cytoplasmic domain of CD4 is applied as a line on a nitrocellulose membrane. A second MAb directed against CD4 and labeled with biotin is dried onto a blood collection pad. Whole blood is added directly to the VISITECT CD4 test where it mixes with the biotin-labeled MAb. Red blood cells and monocytes are retained in the blood collection pad and, following the addition of running buffer, other white blood cells (including CD4+ T-cells) migrate to a reaction area where cell lysis occurs, resulting in the release of full-length CD4 for capture and detection on the test strip. Colloidal gold-labeled anti-biotin antibody detects the complexes of full-length CD4 and biotin-labeled antibody at the test line. A reference control line is included to allow estimation of CD4 levels by comparison to a set cut-point (e.g. the signal level generated by samples containing 350 cells/µL).	**Sample type**	Capillary and venous (EDTA) whole blood
		Sample volume	30µL
		Sample stability	Less than 24 hour old blood sample
		Time to result	40 minutes
		Capacity	N/A
		Batching?	Possible
		Throughput per end-user per hour and/or 8hr day	Up to 120 samples/day
		INSTRUMENT (OPTIONAL AX-2X STRIP READER)	
		Size of device	W 123 x H 113 x D 109 mm
		Weight of device	600g
		Robustness	Robust
Type of result	Semi-quantitative	**Environmental requirements**	5 - 45°C
Linear range	To be determined.	**Power requirements**	12V DC / 100-240 V, 50 Hz AC/DC supplied plug pack
Output	Visual or optional instrument estimation of line intensity for sample under test compared to a reference line, the intensity of which is designed to match that of a particular CD4 cells/µL, for example, 350 CD4+ T cells/µL.	**Time to battery charge**	N/A
		Battery duration (hours)	N/A
T-cell specific?	Yes	**Alternative charging options**	12 V DC Battery Pack, 12 V DC Rechargeable Solar Battery Pack
Polyvalency	No	**Ease of use**	3.4 LCD colour touch screen (pictogram & keypad). USB printer is optional.
PERFORMANCE		**Display languages**	English, French, Portugese, Spanish, Italian, German
Accuracy (source)	Not provided	**Built-in memory storage capacity**	1,000 Patient Records
		Connectivity options	Multiple data export options
Bias - CD4 counts, adults (source)	N/A	**Interpretation of result**	Above or below cut-off reference (e.g. 350 cells/µL)
Bias - CD4 counts & %, children (source)	N/A	**Instrument lifespan**	5 years (reader)
Intra-assay precision, counts & % (source)	N/A (single use test)	**Other non-proprietary equipment required**	None
Inter-assay precision, counts & % (source)	To be determined	**Regulatory approval**	Not available for reader.

Continued overleaf

Point-of-Care CD4 – Omega Diagnostics continued

KIT		USAGE	
Kit components	CD4 strip test, running buffer, lancets, swabs, micro-pipette, desiccant, instructions for use.	**Technical skill required**	Trained health professional or health care worker.
Kit sizes	25 test packs	**Applicable settings**	Primary Health Care level zero and above.
Internal control(s)	A procedural control is built in to the test.	**Laboratory set-up**	None required
Compatible with EQA and which?	No	**Waste disposal requirements**	Disposal by incineration of infectious disease materials; simple trash for other materials.
Mean time between failures	N/A		
Transport and storage	Indicative transport and storage under ambient temperatures to be confirmed by ongoing long term stability data.		
Fridge at -80°C required?	No		
Shelf life (of each item in the kit)	To be determined by on going long term stability trial data.		
Performance protocol (steps)	(1) Collect capillary blood sample; (2) Fill tube with blood; (3) Squeeze sample on to strip test; (4) Add buffers and incubate; (5) Read result.		
Non-proprietary components required outside of the kit	None		
Regulatory approval	Pending		
In-country approvals	In progress		

02 | PRICING

POC Test Kits		**Reference number**	**FCA ($)**
Visitect CD4 Plus 350	25 Test Kit	OD296	$130
Visitect CD4 Plus 350	100 Test Kit	OD396	$520
Optional Reader		**Reference number**	**FCA ($)**
Visitect AX-2X Reader	1 Unit	OD 286	$3,500
Cost per device	**$3,500**	**Cost per test result**	**$5.2**

Intellectual property		
Patent Numbers		Legal Status
Primary Patent Information	PCT/AU2007/001449 Title: 'A method of diagnosis and kit therefore.'	Granted
National Phase Information of the Primary Patent	Australia AU2007302626	Granted
	Canada CA2664698	Pending
	European Patent Office EPO7815265.9	Pending
	USA US8409818	Granted
	South Africa ZA2009/02151	Granted
	African Regional IP Office AP2703	Granted
	Organisation Africaine de la Propriété Intellectuelle 14479	Granted
	China CN101558309.B	Granted

03 | TIERED AND VOLUME-BASED PRICING

No tiered pricing is in place for the test consumables. Volume based pricing is offered on the reader with a single unit at US$3,500; 10+ readers at US$3,000 each and 100+ readers at US$2,500 each.

04 | MAINTENANCE, WARRANTY & TRAINING

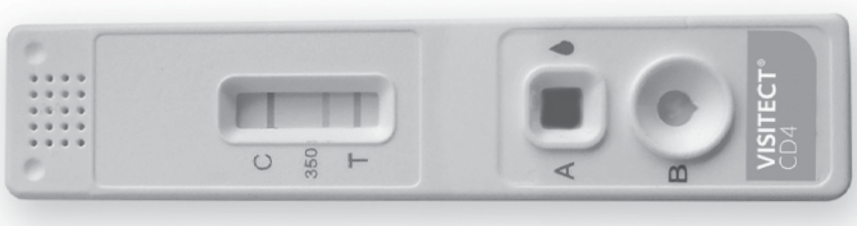
	Description	Cost (US$)
Leasing or reagent rental (RAP)	N/A	
Installation	For optional reader: 1/2 day.	Included
Training	2-day on-site 'train the trainer' course and local workshops for POC device to include: PowerPoint / Training Manuals / Bench Materials / Wall Posters / Training Video (YouTube)	Included, but local costs such as transportation and living expenses to be handled by the recipient.
Maintenance	Optional instrument is maintenance-free. Swap out if required during 12-month warranty period.	
Length(s) of warranty and additional costs for extended warranty / care plan	N/A	
Warranty components	N/A	
Turnkey option	N/A	
In-country / regional technical support availability	Yes. Initially from Cape Town.	

05 | CONTACT INFO

John Bannister
Global Health Business Development Director

Omega Diagnostics Ltd
Omega House
Hillfoots Business Village
Alva, Clackmannanshire
FK12 5DK United Kingdom

Website: omegadiagnostics.com
Tel: +44 (0) 1259 763030
Mobile: +44 (0) 7964 901590



POINT-OF-CARE CD4
SYSMEX PARTEC

01 | TECHNICAL AND PERFORMANCE INFORMATION

Company	SYSMEX PARTEC GmbH	Product	CyFlow® miniPOC
ASSAY		**SAMPLE**	
Intended use (as per regulatory approval)	Determination of CD4 absolute and CD4% in human whole blood samples.	**Sample type**	Venous whole blood; EDTA as anticoagulant
Principle of the assay	Single platform flow cytometry based on TVAC.	**Sample volume**	20 µl whole blood sample
Type of result	Quantitative, absolute count and percentage.	**Sample stability**	48 hours at 2 - 8°C
Linear range	5 - 5,000 cells/µL	**Time to result**	3 minutes for counting analysing and saving, sample attached to the instrument; 15 minutes incubation time outside the instrument.
Output	CD4 absolute (CD4+ T-lymphocytes/µL), CD4% (CD4+ T-lymphocytes among all lymphocytes).	**Capacity**	Approx. 20 tests per hour
T-cell specific?	Yes, fluorochrome conjugated CD4/CD45 mAb.	**Batching?**	Batching samples is possible.
Polyvalency	No	**Throughput per end-user per hour and/or 8hr day**	Approx. 160 tests per day
PERFORMANCE		**INSTRUMENT**	
Accuracy (source)	Refer to PLOS ONE DOI:10.1371/journal.pone.0116848 January 26, 2015; PLOS ONE DOI:10.1371/journal.pone. 0116663 February 17, 2015	**Size of device**	W/D/H [mm] 270/188/240
Bias - CD4 counts, adults (source)	Mean relative bias : < 5% (published PLOS ONE 0116663)	**Weight of device**	6.2kg
Bias - CD4 counts & %, children (source)	Mean absolute bias : < 1 % (published PLOS ONE 0116663)	**Robustness**	Robust, no laser alignment after transport necessary.
Intra-assay precision, counts & % (source)	For samples with CD4 T-cell concentration > 200 cells/µl intra assay precision ≤ 10%; Samples with CD4 T-cell concentration < 200 cells/µl intra assay precision ≤ 15% (internal study)	**Environmental requirements**	Temperature: 15 - 30°C (operative) Humidity: 20 - 85% relative (non-condensing)
Inter-assay precision, counts & % (source)	For samples with CD4 T-cell concentration > 200 cells/µl intra assay precision ≤ 10%; Samples with CD4 T-cell concentration < 200 cells/µl intra assay precision ≤ 15% (internal study)	**Power requirements**	- 100/230 VAC power supply - 50/60 Hz; - Battery Pack for CyFlow® miniPOC / CY-S-3096
SAMPLE		**Time to battery charge**	3 hours
Sample preparation (steps)	(1) 20µl EDTA blood has to be transferred into the ready-to-use CD4/CD45 dry mAb reagent tube and shaken by hand for approximately 3 seconds, then stored in the dark for 15 minutes (during this incubation time, in parallel other blood samples can be processed in batches). (2) The ready-to-use prefilled buffer solution "Buffer 1" has to be added (no pipetting required). (3) Prior to analysis, the ready-to-use prefilled buffer solution "Buffer 2" has to be added (no pipetting required). The sample must be transferred into the plastic disposable syringe (no pipetting required), which will be placed at the sample port of the device, and analysis can be started. (4) The result of the measurement will be automatically displayed and stored on the hard disk drive of the instrument as well as printed by the built-in thermo transfer printer.	**Battery duration (hours)**	Battery Pack for CyFlow® miniPOC 4-5 hours operating time
		Alternative charging options	- Set to connect with car battery is standard equipment - Battery Pack for CyFlow® miniPOC / CY-S-3096 - Solar Panel for Battery Pack for CyFlow® miniPOC / CY-S-3099
		Ease of use	- Built-in computer - "5.7" TFT colour touchscreen - Automated analysis - Automated data saving - Built-in thermal printer
		Display languages	English, French, Spanish and German.
		Built-in memory storage capacity	Data storage of approximately 20,000 data sets.
		Connectivity options	USB
		Interpretation of result	- CD4 in cells/µL - CD4% - Lymphocytes in cells/µL
		Instrument lifespan	Expected life span 8 years
		Other non-proprietary equipment required	No
		Regulatory approval	- CE (TÜV) IVD (Directive 98/79/EG) - Not eligible as POC for GF ERPD - Submission of product dossier for WHO PQ is on-going

KIT		USAGE	
Kit components	05-8409-d Partec miniPOC CD4% count kit – dry, 20 tests, includes: - 20 Sample tubes with pre-filled dry CD4/CD45 mAb reagents - 20 Test tubes pre-filled with Buffer 1 - 20 Test tubes pre-filled with Buffer 2 - 2 Sheath Fluid containers - 2 bottles of Sheath Fluid (each 250mL) - 20 Pipette tips (2 - 200µL) - 5 Sample tubes with pre-filled Count Check Beads green – dry - 5 Test tubes pre-filled with Rehydration Solution for Count Check Beads green – dry - 2 Tubes with Cleaning Solution (each 5mL) - 1 Tube with Decontamination Solution (5mL) - 1 Roll Thermo Printer Paper - 40 Syringes - Quality Check Protocol	**Performance protocol (steps)**	(1) Sample staining, (2) Incubation (15 min), (3) Adding buffers, (4) Sample run, (5) Data analysis and results (automated).
		Non-proprietary components required outside of the kit	None.
		Regulatory approval	CE,TÜV, In Vitro Diagostics Directive 98/79/EG (IVD)
Kit sizes	20 tests/kit	**In-country approvals**	In-country registration available through local distributors/affiliates.
Internal control(s)	Supports internal QC (Partec Count Check Beads as non-biological controls).	**Technical skill required**	Technical skill required for laboratory staff: nurse or lab technician.
Compatible with EQA and which?	EQA programs: National Health Laboratory Service; COE Center of Excellence for Flow Cytometry	**Applicable settings**	Technology can be used at all levels of the health system, including central, regional, district and mobile labs, and some primary sites.
Mean time between failures	Proprietary.		
Transport and storage	Recommended transport temperature: +2°C to +35°C, do not freeze; Recommended storage temperature: +2°C to +8°C, do not freeze	**Laboratory set-up**	Clean desk or table.
Fridge at -80°C required?	No	**Waste disposal requirements**	According to the local regulations.
Shelf life (of each item in the kit)	Min. 6 months.		

02 | PRICING

Instrument	**Reference number**	**FCA ($)**	**Cartridge/reagents**		**Reference number**	**FCA ($)**
CyFlow® miniPOC consisting of: CY-S-3033 / CyFlow® miniPOC	CY-S-3033	$10,982.90 (including user training of $1,515.15)*	Partec miniPOC CD4% count kit - dry (20 tests)		05-8409-d	$66.60*
CyFlow® miniPOC Set Reagents Starterkit consisting of: 05-8409-d Partec miniPOC CD4% count kit- dry (20 tests) 04-6-1023 Eppendorf Pipette fix 20µl 04-2000-03 sample Tubes Rack for Cy-Flow® MiniPOC 04-412 Hypochlorite Solution (250 ml) 04-100-1038 Preventive Maintenance Kit No. 03	CYS-3033_REAG	$440.3*				
Instrument Accessories	**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
Transportation Bag for CyFlow® miniPOC	CY-S-3091	$358.53*	N/A			
Battery Pack for CyFlow® miniPOC	CY-S-3096	$388.50*				
Solar Panel for Battery Pack for CyFlow® miniPOC	CY-S-3099	$310.80*				
Price per instrument			**Price per test result**			**$3.33***

*Additional Clause:
- Exchange Rate: EUR 1,00 = USD 1.11
- If the exchange rate fluctuates by 10%, we reserve the right to adjust the prices

Continued overleaf

Point-of-Care CD4 – Sysmex Partec continued

03 | TIERED AND VOLUME-BASED PRICING

Instrument		Test kit	
Volume	**FCA ($)**	**Volume tier per tests per year**	**FCA ($)**
Available on request		Available on request	

04 | MAINTENANCE, WARRANTY & TRAINING

	Description	Cost (US$) (FCA)
Leasing or reagent rental (RAP)	Reagent rental options can be inquired in a partnership approach with the local distributor.	Upon request.
Installation	The CyFlow® miniPOC Instructions for Use (IFU) provides all the information for set-up, instrument operation and maintenance.	
Training	Common training procedure: 1. 6 hours (1 day) on site training will be offered by Sysmex Europe trained local distributor. Also, centralised training programmes and training seminars are available on demand. 2. English and local languages are on request 3. Yes 4. Power Point, Instruction for Use, Product Insert Sheet 5. Capacity to perform tests as a trained person	Training is in price of CY-S-3033 included.
Maintenance (including instrument swap)	Service/maintenance: usual response time for service/maintenance is two working days under normal conditions. Depending on very specific factors, longer response times may be possible. For any support, service or maintenance inquiry, the responsible local service provider should be contacted.	Besides regular warranty coverage, preventive maintenance and service contracts can be requested at local service provider (Sysmex affiliates/ distributors).
Length(s) of warranty and additional costs for extended warranty / care plan	Common Warranty: 12 months (preventive maintenance and service contracts optionally available on request).	
Warranty components	Common Warranty: 12 months on all parts except filters, mirrors, other quartz or glass parts, disposables, as long as not otherwise stated.	
Turnkey option	Available on request.	
In-country / regional technical support availability	Available through Sysmex trained in-country distributors (first level support - available nearly in all countries), and through Sysmex regional affiliates (second level support - Sysmex Training Centres for South-East Africa as well as Central-West Africa and one Support Hub for East Africa)	Upon request.

05 | CONTACT INFO

Ms. Ute Wagner-Douglas
Product Manager

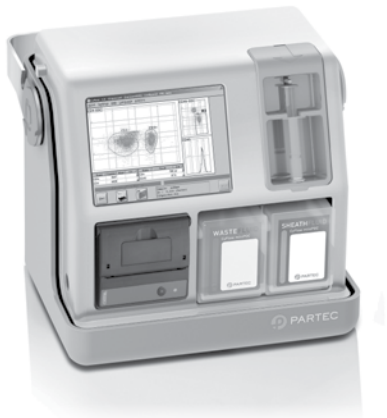
Sysmex Partec GmbH, Otto-Hahn-Straße 32, 48161 Münster, Germany

Website: www.sysmex-partec.com
Tel: +49 2534 8008 110
Email: Wagner-Douglas.Ute@sysmex-partec.com

Mr. Mario Geißler
Public Health Key Account Manager

Sysmex Partec GmbH, Bornbarch 1, 22848 Norderstedt, Germany

Website: www.sysmex-europe.com/products/diagnostics/essential-healthcare.html
Tel: +49 3581 87 46 553
Email: geissler.mario@sysmex-europe.com



POINT-OF-CARE HIV EID
ALERE

01 | TECHNICAL AND PERFORMANCE INFORMATION

Company	ALERE	Product	ALERE Q HIV 1/2 DETECT
ASSAY		**SAMPLE**	
Intended use (as per regulatory approval)	EID and acute stage adult diagnosis.	**Sample preparation**	None
		Sample type	Whole blood (capillary or venous EDTA) & plasma EDTA.
Principle of the assay	Multi-plexed real time PCR.	**Sample volume**	25µL
Target	Proprietary	**Sample stability**	Venous whole blood, collected into EDTA tubes, can be stored at: - Ambient temperature (18 - 28°C) for ≤24 hours after draw. - Otherwise aliquoted and frozen at -80°C immediately after draw (there is no need to generate plasma before freezing). - Frozen samples should be thawed at ambient temperature and, once thawed, tested immediately (invert the thawed sample tubes 10-15 times before pipetting).
Genotypes and/ or subtypes	HIV-1 (M/N), HIV-1 (O) & HIV-2	**Nucleic acid extraction method**	Automated (in cartridge)
Type of result	Qualitative	**Time to result**	52 minutes
Linear range	N/A	**Capacity**	1 test at a time
Output	Detected or not detected.	**Batching?**	No
DNA or RNA specific?	RNA	**Throughput per end-user per hour and/or 8hr day**	8/day
Polyvalency	In development	**INSTRUMENT**	
PERFORMANCE		**Size of device**	20 x 22 x 31 cm
Sensitivity - analytical and clinical (source)	Venous blood: 98.98% Capillary blood: 98.65% Plasma: 99.57% (V&V Studies Pack insert)	**Weight of device**	7.8 kg
		Robustness	Very robust.
Specificity - analytical and clinical (source)	100% (V&V Studies Pack Insert)	**Environmental requirements**	Temperature: 10 - 40°C Humidity: 0 - 85% Altitude: 0 - 2,000 m NN
Bias (source)	N/A	**Power requirements**	100 - 240 V at 50 - 60 Hz
Intra-assay precision (source)	N/A	**Time to battery charge**	Recommended: overnight
Inter-assay precision (source)	To evaluate precision, 6 HIV negative whole blood samples from cohort G were spiked with virus preparations of HIV-1 group M subtype B (strain IIIB) at a concentration of 8,000 copies/mL. For all 348 tests on spiked venous whole blood samples performed on 8 different Alere q analysers over the course of 6 days, HIV-1 M/N was 100% successfully detected. There were no false positive results for HIV-1 O and HIV-2. The results are considered to be representative for all analytes of the Alere q HIV-1/2 Detect test (HIV-1 group M/N, HIV-1 group O and HIV-2).	**Battery duration (hours)**	1 hour
		Alternative charging options	External battery giving 6-7 hours.
		Ease of use	Touch screen, optional USB printer.
		Display languages	English, French, German, Portuguese, Spanish.
		Built-in memory storage capacity	1,000 tests
		Connectivity options	USB cellular modem with datapoint connectivity, LAN.
		Interpretation of result	Printed as detected or not detected.
		Instrument lifespan	Alere guarantee 10 years.
		Other non-proprietary equipment required	No
		Regulatory approval	GF ERPD, CE-IVD & WHO PQ.

Continued overleaf

Point-of-Care HIV EID – Alere continued

KIT		USAGE	
Kit components	50 foiled cartridges	**Technical skill required**	No
Kit sizes	50 tests	**Applicable settings**	Point-of-care and small laboratories.
Internal control(s)	Yes	**Laboratory set-up**	None required.
Compatible with EQA and which?	Compatible WHO panel, QASI EID.	**Waste disposal requirements**	Standard biohazard waste disposal.
Mean time between failures	Proprietary		
Transport and storage	4 - 30°C		
Fridge at -80°C required?	No		
Shelf life (of each item in the kit)	9 months (currently)		
Performance protocol (steps)	None		
Non-proprietary components required outside of the kit	No		
Regulatory approval	GF ERPD, CE-IVD & WHO PQ.		
In-country approvals	Speak to local representative.		

02 | PRICING

Depends on volume tier & deployment conditions.

Prices quoted to MSF for 2015. Alere aim to provide the same pricing to all global humanitarian and development stakeholders, however please consider pricing as indicative only.

Instrument		Reference number	EXW ($)
Alere q Analyser Complete	Includes Instrument, Power Drum, Modem, Printer	270300002	$25,000

Instrument Accessories	Reference number	EXW ($)
None		

Cartridge/reagents		Reference number	EXW ($)
Alere q HIV 1/2 Detect	50 Tests	270110050	$747.50 - 1,250 (depending on tier)

Non-proprietary equipment and consumables		Reference number	EXW ($)
Optional Extras:			
Finger Stick Sample Collection Kit	100 Tests	260400199	$100
Neonatal Sample Collection Kit	100 Tests	270400200	$120
Pima Printer Paper 1 (same for Alere q)	10 rolls	260400009	$32
Pima Printer Paper 2 (same for Alere q)	10 rolls	260400010	$180
Plastic Capillaries Plane	1,000	270400005	$180
Plastic Capillaries ETDA-K2	1,000	270400006	$180

Cost per device	$25,000	Cost per test result	≥$14.95 - 25

03 | TIERED AND VOLUME-BASED PRICING

Instrument	Assay cartridge/kit	
The complete instrument costs $25,000 Ex Works. If customers procure 25 or more instruments on a single PO that is shipped to a single country then Alere will offer an additional 2-year warranty (valued at $5,000) FOC.	**Volume tier per tests per year**	**Ex Works ($) per test (50 Tests per Kit)**
	0 - 199,999	$25
	200,000 - 399,999	$22.50
	400,000 - 599,999	$19.95
	600,000 - 799,999	$17.95
	≥800,000	$14.95
	Only individual organisation orders will count towards the tiers and consumption will be reviewed quarterly.	

04 | MAINTENANCE, WARRANTY & TRAINING

	Description	Cost (US$)
Leasing or reagent rental (RAP)	No RRP offered at this stage.	
Installation	None required.	
Training	- Training will be provided in country on a regional/national basis. - Half a day is required.	Training is included in the purchase price.
Maintenance	None required but warranty includes instrument swap.	
Length(s) of warranty and additional costs for extended warranty / care plan	12 months, after which a Care Plan can be procured.	$2,500 per year
Warranty components	Labour, parts and a swap instrument.	
Turnkey option	None required.	
In-country / regional technical support availability	- Alere offer a tiered system. - Certain repairs can be done in country while others would be done regionally at Alere's hubs. - Customers will receive a swap device while their device is in for repair.	

05 | CONTACT INFO

Wajid Shafique
Global Product Manager - HIV Care

Alere Limited
Pepper Road, Hazel Grove
Stockport, SK7 5BW
UK

Website: www.alerehiv.com
Tel: +44 (0)161 483 5884
Mobile: +44 (0)7894 613 994
Email: wajid.shafique@alere.com

POINT-OF-CARE HIV EID, HIV VL, HCV VL
CEPHEID

01 | TECHNICAL AND PERFORMANCE INFORMATION

	HIV EARLY INFANT DIAGNOSIS	HIV VIRAL LOAD	HCV VIRAL LOAD
Company	**Cepheid**		
Product	**XPERT HIV-1 QUAL**	**XPERT HIV-1 VIRAL LOAD**	**XPERT HCV VIRAL LOAD**
ASSAY			
Intended use (as per regulatory approval)	In vitro diagnostic test designed to detect HIV-1 total nucleic acids from individuals suspected of HIV-1 infection. Intended to aid in the diagnosis of HIV-1 infection in conjunction with clinical presentation and other laboratory markers.	In vitro diagnostic test designed for the rapid quantitation of HIV-1 from HIV-1 infected individuals. Intended for use in conjunction with clinical presentation and other laboratory markers for disease prognosis and for use as an aid in assessing viral response to antiretroviral treatment, as measured by changes in plasma HIV-1 RNA levels. Not intended to be used as a donor screening test for HIV-1 or as a diagnostic test to confirm the presence of HIV-1 infection.	In vitro diagnostic test designed for the rapid quantitation of HCV RNA from HCV infected individuals. Intended for use as an aid in the management of HCV-infected patients undergoing antiviral therapy. The test measures HCV RNA levels at baseline and during treatment and can be utilized to predict sustained and nonsustained virological response to HCV therapy. The results should be used in conjunction with clinical presentation and other laboratory markers and findings. Not intended to be used as a donor screening test for HCV or as a diagnostic test to confirm the presence of HCV infection.
Principle of the assay	GeneXpert Instrument Systems automate and integrate sample preparation, nucleic acid extraction and amplification, and detection of the target sequences in simple or complex samples using real time reverse transcription PCR (RT-PCR). The systems consist of an instrument, personal computer, and preloaded software for performing tests and viewing the results. The systems require the use of single-use disposable GeneXpert cartridges that hold the RT-PCR reagents and host the RT-PCR processes. Because the cartridges are self-contained, cross-contamination between samples is minimized. For a full description of the system, see the GeneXpert Dx System Operator Manual or the GeneXpert Infinity System Operator Manual. The assays include reagents for the detection of nucleic acids in specimens as well as an internal control to ensure adequate processing of the target and to monitor the presence of inhibitor(s) in the RT and PCR reactions. The Probe Check Control (PCC) verifies reagent rehydration, PCR tube filling in the cartridge, probe integrity, and dye stability. A sample adequacy control ensures sufficient sample has been added for accurate viral load measurement.		
Target	3′-end of 5′ LTR		5′ UTR
Genotypes and/ or subtypes	HIV-1, Group M Subtypes A-H, AB, AE, AG, J, K, Group N, Group O.		Genotypes 1-6
Type of result	Qualitative	Quantitative	Quantitative
Linear range	N/A	40 – 10,000,000 HIV-1 copies/mL	10 – 100,000,000 HCV IU/ml
Output	HIV infected / HIV uninfected	copies/mL	IU/mL
DNA or RNA specific?	TNA	TNA (RNA from plasma)	RNA
Polyvalency	MRSA/Staph aureas, C. difficile, vanA, norovirus, MTB/RIF, Flu/RSV, EV, CT/NG, GBS, FII & FV, and a number of others (see full menu).		
PERFORMANCE			
Sensitivity - analytical and clinical (source)	Not provided.		

Product	XPERT HIV-1 QUAL	XPERT HIV-1 VIRAL LOAD	XPERT HCV VIRAL LOAD
PERFORMANCE (CONTINUED)			
Specificity - analytical and clinical (source)	**Analytical specificity:** - Evaluated by adding cultured organisms at 5 x 10^3 particles or cp/mL into HIV-1 negative EDTA whole blood and into HIV-1 positive EDTA whole blood at 900 cp/mL HIV-1 reference material (subtype B). Organisms were tested using the whole blood procedure. - Tested organisms are listed: Candida albicans, Cytomegalovirus, Epstein-Barr virus, hepatitis A virus, hepatitis B virus, hepatitis C virus, herpes simplex virus 1, herpes simplex virus 2, human herpesvirus 6, HIV-2, human T-cell lymphotropic virus type 1, human T-cell lymphotropic virus type 2, influenza A, Staphylococcus aureus. None of the organisms tested showed cross reactivity or interference with the HIV-1 detection. **Clinical specificity:** - Whole blood collected in EDTA was collected from 1,017 blood donors at two sites in the United States (Washington and Minnesota). The specimens were determined to be HIV-1 negative by standard blood bank FDA-licensed antibody and nucleic acid methods. - Of the 1,017 specimens, 503 were prepared as DBS and 514 were tested as whole blood. One DBS and two WB specimens were indeterminate on both initial and retest, and therefore excluded from the specificity calculation. - The specificity was 100% (1014/1014), 95% CI: 99.6-100.0.	**Analytical specificity:** - Evaluated by adding cultured organism at 5 x 10^4 particles or cp/mL input concentration into HIV-1 negative EDTA plasma and in plasma that contained 1,000 cp/mL HIV-1 reference material (HIV-1 subtype B). - Tested organisms are listed: HIV-1, HIV-2, Human T-cell lymphotropic virus I, Human T-cell lymphotropic virus II, Candida albicans, Cytomegalovirus, Epstein-Barr virus, hepatitis A virus, hepatitis B virus, herpes simplex virus 1, herpes simplex virus 2, human herpes virus 6, human herpes virus 8, Varicella zoster virus, BK Human polyoma virus, Banzi virus, Ilheus virus, West Nile virus, Zika virus, human papilloma virus 16, human papilloma virus 18, Staphylococcus pidermis, Staphylococcus aureus. None of the organisms tested showed cross reactivity and all HIV-1 positive replicates resulted in a titer within ± 0.5 log of the HIV-1 positive control. **Clinical specificity:** - Evaluated using 109 EDTA plasma specimens from HIV-1 negative blood donors. - None of the 109 specimens tested were detected equating to 100% specificity (95% CI = 96.7–100.0).	**Analytical specificity:** - Evaluated by adding potentially cross-reacting organisms at 1 x 10^5 CFU/mL, copy/mL or TCID 50/mL input concentration into HCV negative EDTA plasma and in plasma that contained ~25 IU/mL HCV reference material (clinical specimen genotype 1). None of the tested organisms showed cross reactivity and all positive replicates resulted in concentrations of HCV RNA within ± 0.5 log from a HCV positive control. - In addition to the species listed here, HIV-1, HIV-2, Human T-cell lymphotropic virus I, Human T-cell lymphotropic virus II, Candida albicans, Cytomegalovirus, Epstein-Barr virus, hepatitis A virus, hepatitis B virus, herpes simplex virus 1, herpes simplex virus 2, human herpes virus 6, human herpes virus 8, Varicella zoster virus, BK Human polyoma virus, Banzi virus, Ilheus virus, West Nile virus, Zika virus, human papilloma virus 16, human papilloma virus 18, Staphylococcus epidermis, Staphylococcus aureus, Dengue virus and vaccinia virus were analysed in silico since material representing the viruses could not be obtained for testing. No practical significant sequence similarity was found between the analyzed viruses and the primers and probes of the assay.
Bias (source)	Not provided.		
Intra-assay precision (source)	Not provided.	Total precision: - 1.6 log10 cp/mL: SD 0.25, CV 62.5% - 3 log10 cp/mL: SD 0.09, CV 20.5% - 5 log10 cp/mL: SD 0.08, CV 17.8% - 7 log10 cp/mL: SD 0.10, CV 22.6%	Total precision: - 1.0 log10 cp/mL: SD 0.21, CV 51.7% - 2.7 log10 cp/mL: SD 0.09, CV 22.1% - 5.4 log10 cp/mL: SD 0.11, CV 25.8% - 8.2 log10 cp/mL: SD 0.13, CV 30.5%
Inter-assay precision (source)	VQA Reference Standard: - WB: 88 - 96% ≥200 copies/mL - DBS: 100% ≥800 copies/mL WHO Reference Standard: - WB: 100% ≥420 copies/mL - DBS: 96 - 100% ≥1,000 copies/mL		
SAMPLE			
Sample preparation (steps)	Processing DBS requires a 15 min incubation at 56°C in a thermometer rotating at 500rpm. The eluate is then transferred into the cartridge. WB does not require any preparation.	Prepare plasma.	Prepare plasma or serum.
Sample type	Whole Blood or DBS	EDTA, EDTA-PPT plasma, ACD plasma	EDTA, EDTA-PPT plasma or serum
Sample volume	100µL WB or 1 DBS (50-70µL)	1mL plasma	1mL serum or plasma
Sample stability	• EDTA-anticoagulated whole blood may be stored at - 31–35°C for ≤8 hours - 15–30°C for ≤24 hours - 2–8°C for ≤72 hours • DBS cards may be stored at - ≤31–35°C for ≤8 weeks - 2-25°C or -15 °C or colder for up to 12 weeks	Whole blood may be held at 15–30 °C for up to 8 hours, 15–25 °C for up to 24 hours or at 2–8 °C for up to 3 days, prior to preparing and testing the specimen. • After centrifugation, plasma may be held at 15–30 °C for up to 24 hours or at 2–8 °C for up to 6 days, prior to testing. • Plasma specimens are stable frozen (≤ -18 °C and ≤ -70 °C) for 6 weeks. • Plasma specimens are stable for up to three freeze/thaw cycles. • Plasma specimens must be thawed and equilibrated to room temperature prior to transfer to cartridge.	Whole blood may be held at 15–35 °C for 6 hours, at 15–25 °C for 24 hours or at 2–8 °C for up to 72 hours prior to preparing and analyzing the specimen. • After centrifugation, plasma and serum may be held at 15–35 °C for 24 hours or at 2–8 °C for three days prior to testing. • Plasma and serum specimens are stable frozen (-70 to -18 °C) for 6 weeks. • Plasma and serum specimens are stable for up to three freeze/thaw cycles.
Nucleic acid extraction method	Automated		
Time to result	90 minutes		105 minutes
Capacity	**Time (hours)** **8** **10** **12** **24** 1 module 6 7 8 16 2 modules 12 14 16 32 4 modules 24 28 32 64 16 modules 96 112 128 256		
Batching?	No		
Throughput per end-user per hour and/or 8hr day	**8hr throughput/m²:** 1 module 190 4 modules 289 2 modules 250 16 modules 494		

Continued overleaf ⋰

Product	XPERT HIV-1 QUAL	XPERT HIV-1 VIRAL LOAD	XPERT HCV VIRAL LOAD
	INSTRUMENT		
Size of device	1 module W 10.60 x H 30.48 x D 29.72 cm 2 modules W 16.13 x H 30.48 x D 29.72 cm 4 modules W 27.94 x H 30.48 x D 29.72 cm 16 modules W 57.79 x H 65.53 x D 33.66 cm		
Weight of device	1 module: 8.16 kg 4 modules: 12 kg 16 modules: 57 kg		
Robustness	Systems are robust with minimal maintenance/cleaning. In routine use at many TB centres globally.		
Environmental requirements	15 - 30°C		
Power requirements	220-240V, 50-60 Hz - 110V version also available		
Time to battery charge	N/A		
Battery duration (hours)	N/A		
Alternative charging options	Solar panel installations have been demonstrated as well as inverters linked to arrays of lead/acid batteries.		
Ease of use	No internal printer. USB printer can be added to print all of the parameters mentioned.		
Display languages	Choice of English, French, German, Italian, Spanish, Portuguese, Russian and Mandarin selected at installation.		
Built-in memory storage capacity	None, other than laptop, or desktop computer.		
Connectivity options	Ethernet, Wifi and USB ports. Communications protocols for HL7 and ASTM standards are included in the GeneXpert software. Remote Xpert software available for download.		
Interpretation of result	The instrument will display Positive, Negative, Invalid, Error or 'No Result' if the process is interrupted by the user.	The instrument will display: - HIV detected XX copies/mL - HIV detected <40 copies/mL - HIV Detected >1x10^7 copies/mL - HIV not detected - Invalid, Error or 'No Result', if the process is interrupted by the user	The instrument will display: - HCV detected XX IU/mL - HCV detected <10 IU/mL - HCV detected >1x10^8 IU/mL - HCV not detected - Invalid, Error or 'No Result', if the process is interrupted by the user
Instrument lifespan	7 Years (except for the computer, which may require updating before this time).		
Other non-proprietary equipment required	Printer, as needed.		
Regulatory approval	FDA Approved	FDA Approved	FDA Approved
	KIT		
Kit components	Each kit contains: - 10 Xpert HIV-1 Qual Assay Cartridges with Integrated Reaction Tubes - Xpert HIV-1 Qual Sample Reagent Set (Sample Reagent) 10, containing 1.0mL Lysis Reagent (Guanidinium Thiocyanate) per vial - 10 Disposable (1mL) Transfer Pipettes - 10 Disposable 100µL Transfer Micropipettes - CD with ADF, PI	Each kit contains: - 10 Xpert HIV-1 VL Assay Cartridges with Integrated Reaction Tubes; - 10 Disposable (1mL) Transfer Pipettes - CD with ADF, PI	Each kit contains: - 10 Xpert HCV VL Assay Cartridges with Integrated Reaction Tubes - 10 Disposable (1mL) Transfer Pipettes - CD with ADF, PI
Kit sizes	10 tests per kit		
Internal control(s)	Each test includes a - Sample Volume Adequacy (SVA) - Sample Processing Control (SPC) - Probe Check Control (PCC)	Each test includes a - Sample Volume Adequacy (SVA) - Internal Quantitative Standard High and Low (IQS-H and IQS-L, also acts a specimen processing control [SPC]) - Probe Check Control (PCC)	
Compatible with EQA and which?	Yes, any.		
Mean time between failures	Not provided.		
Transport and storage	Shipping and storage at ambient temp, 2-28°C.		
Fridge at -80°C required?	No	No, unless for long term storage of plasma.	
Shelf life (of each item in the kit)	12 months at the time of manufacture. Typically, Xpert cartridges are stable for between 12 - 24 months from manufacture depending on the amount of historical stability data available.		

Product	XPERT HIV-1 QUAL	XPERT HIV-1 VIRAL LOAD	XPERT HCV VIRAL LOAD
KIT (CONTINUED)			
Performance protocol (steps)	WB: (1) Transfer 750µL of the sample reagent into the sample chamber of the cartridge using transfer pipette provided; (2) Mix EDTA blood by inverting vial; (3) Transfer 100µL of blood into the sample chamber using micropipette provided; (4) start test within 30 minutes. DBS: (1) Excise one DBS for each specimen; (2) Place one DBS in sample reagent vial (fully submerged); (3) Place in ThermoMixer and incubate for 15 minutes at 56°C and rotate at 500 rpm; (4) Transfer all liquid into sample chamber of cartridge using 1mL transfer pipette provided.	(1) Prepare the specimen; (2) Prepare the cartridge by transferring 1mL of plasma into the sample chamber using the transfer pipette provided; (3) Load cartridge onto GeneXpert and run.	
Non-proprietary components required outside of the kit	If using DBS: • DBS Collection Kit (Filter paper cards, e.g., Whatman 903, Munktell or equivalent, lancets and swabs). • Eppendorf ThermoMixer C (Eppendorf order number 5382 000.015). • Eppendorf SmartBlock (Eppendorf order number 5309 000.007).	Blood collection tube, centrifuge.	
Regulatory approval	CE-IVD marked and WHO PQ	CE-IVD marked and WHO PQ	CE-IVD marked and WHO PQ
In-country approvals			
USAGE			
Technical skill required	Basic		
Applicable settings	All		
Laboratory set-up	Minimal		
Waste disposal requirements	As per local authority.		

02 | PRICING

All prices are based on prepayment.

EARLY INFANT DIAGNOSIS, HIV VIRAL LOAD & HCV VIRAL LOAD

Instrument		Reference number	EXW ($)	Cartridge/reagents		Reference number	EXW ($)
GeneXpert Desktop Instruments	*Modules*			Xpert HIV-1 Qual	10 test per kit	GXHIV-QA-CE-10	$179.50
GeneXpert II	2	GXII-2-D	$11,530	Xpert HIV-1 VL	10 tests per kit	GXHIV-VL-CE-10	$168
GeneXpert IV	2	GXIV-2-D	$11,780	Xpert HCV VL	10 tests per kit	GXHCV-VL-CE-10	$171
GeneXpert IV	4	GXIV-4-D	$17,000				
GeneXpert XVI	4	GXXVI-4-D	$30,680				
GeneXpert XVI	8	GXXVI-8-D	$44,120				
GeneXpert XVI	12	GXXVI-12-D	$57,560				
GeneXpert XVI	16	GXXVI-16-D	$71,000				
GeneXpert Laptop Instruments	*Modules*						
GeneXpert II	2	GXII-2-D	$12,030				
GeneXpert IV	2	GXIV-2-D	$12,280				
GeneXpert IV	4	GXIV-4-D	$17,500				
GeneXpert XVI	4	GXXVI-4-D	$31,180				
GeneXpert XVI	8	GXXVI-8-D	$44,620				
GeneXpert XVI	12	GXXVI-12-D	$58,060				
GeneXpert XVI	16	GXXVI-16-D	$71,500				

Instrument Accessories	Reference number	EXW ($)	Non-proprietary equipment and consumables	Reference number	EXW ($)
For DBS (EID): • Eppendorf ThermoMixer C • Eppendorf SmartBlock	Eppendorf order number 5382 000.015 Eppendorf order number 5309 000.007		For DBS (EID): Collection kit (filter paper cards, lancets, swabs)		
Centrifuge					
Cost per device	**GXIV-4-D**	**$17,000**	**Cost per test result**		**$ 16.80 - 17.95**

Continued overleaf

Point-of-Care HIV EID, HIV VL, HCV VL – Cepheid continued

03 | TIERED AND VOLUME-BASED PRICING

Test kit	HIV Qual	HIV VL	HCV VL
Volume	**EXW ($)**	**EXW ($)**	**EXW ($)**
Ceiling price	17.95	16.80	17.10
500,000 tests/year	17.43	16.08	16.43
1,000,000 tests/year	16.65	15.30	15.65
1,500,000 tests/year	16.08	14.75	15.16
3,000,000 tests/year	14.45	13.10	13.45
4,000,000 tests/year	13.35	11.98	12.35

04 | MAINTENANCE, WARRANTY & TRAINING

	EARLY INFANT DIAGNOSIS, HIV VIRAL LOAD & HCV VIRAL LOAD	
	Description	**Cost (US$)**
Leasing or reagent rental (RAP)	Not for High Burden Developing Country Programme.	
Installation	1-2 hrs for GX-1 to -16 modules 3-5 days for Infinity 80	
Training	1. 2-3 hours of training required 2. Languages available: English, French, German, Italian, Spanish, Portuguese, Russian and Mandarin 3. On site training is available 4. Training tools are available 5. Weblink to training materials is available	N/A
Maintenance (including instrument swap)	Robust system, minimal maintenance required. Daily wiping down of the instrument is recommended.	N/A
Length(s) of warranty and additional costs for extended warranty / care plan	2 years with purchase. Extended warranty available as single year extensions or 3 year extensions.	Example: 3 Year Warranty Extension purchased with system - GXIV-2 $4,500 - GXIV-4 $6,840 - GXXVI-16 $18,504
Warranty components	Parts and labour	
Turnkey option	No information provided.	
In-country / regional technical support availability	Will be available direct from Cepheid, present directly in 15 countries, or through our network of service providers. 24 hour tech support hotline available globally.	

05 | CONTACT INFO

Philippe Jacon, Cepheid President HBDC
Email: phillipe.jacon@cepheid.com

Martin Colla, Cepheid HBDC Program Director, Asia
Email: martin.colla@cepheid.com

Cepheid Europe, Vira Solelh
81470 Maurens-Scopont. France

Website: www.cepheid.com
Tel: +33-563-82-53-00

Gwynn Stevens, Virology Director HBDC, South Africa
Email: gwynn.stevens@cepheid.com

Iain Sharp Paul, Cepheid Commercial Director, South Africa
Email: iain.sharp@cepheid.com

Kildrummy Office Park, Famous Grouse House, Kildrummy Office Park
Cnr Witkoppen Road and Umhlanga Avenue, Paulshof, 2191

Website: www.cepheid.com
Tel: +27 11 234 9636

01 | TECHNICAL AND PERFORMANCE INFORMATION

	HIV EARLY INFANT DIAGNOSIS	
Company	**Diagnostics for the Real World, Ltd**	
Product	**SAMBA I HIV-1 QUAL WHOLE BLOOD TEST**	**SAMBA II HIV-1 QUAL WHOLE BLOOD TEST**
	ASSAY	
Intended use (as per regulatory approval)	Qualitative detection of HIV-1 as an aid in the diagnosis of HIV-1 diagnosis in paediatric samples for early infant diagnosis.	
Principle of the assay	Performing the test is divided into two steps: sample preparation and sample testing (amplification/detection). The first step is the extraction of the target RNA/DNA using an automated sample preparation procedure in the SAMBAprep instrument. The procedure lyses the virus and releases the nucleic acid, which is then captured onto a silica membrane in a column. The column with the bound nucleic acid is then washed, followed by elution of the nucleic acid into the Output Tube. The Output Tube is then transferred into the SAMBAamp instrument for the amplification and detection steps. The SAMBAamp cartridge and Reagent Tube are placed into the SAMBAamp instrument. Detection buffer is added to the colour-labeled anti-hapten sphere in the SAMBAamp cartridge. The sample is transferred from the Output Tube to the Reagent Tube, heated, and then transferred to the hermetically sealed SAMBAamp cartridge previously placed in the SAMBAamp instrument. The SAMBAamp cartridge contains all the reagents required to amplify HIV-1nucleic acids in the SAMBAamp instrument. At the end of the amplification cycle,the Detection Buffer is added to the sample by depressing the plunger on the SAMBAamp cartridge and the amplified sample is then wicked up on the Test Strip by capillary action within the SAMBAamp cartridge, giving a visual readout of the result.	The test is a fully automated assay run on the SAMBA II instrument system consisting of the SAMBA II Assay Module, and a control unit – the SAMBA II Tablet module. Nucleic acid extraction, amplification of the nucleic acid target and the detection of the amplification products are performed in the SAMBA II Assay Module. The extraction phase of the assay involves the lysis to release nucleic acid (proviral DNA and RNA) into solution, which is then captured by a silica membrane column. The bound nucleic acid is washed and eluted from the membrane and the HIV target sequence is amplified in the sealed cartridge. After amplification, a coloured-labeled anti-hapten detection solution is mixed with the amplification product and the mixture is wicked in a Test Strip. The test result (i.e. bluish to purple lines on the Control Line and/or Test Line) is captured by a built-in camera, which is recorded and can be read on the Tablet module. Results are stored and may be printed from the Bluetooth printer. Results can be sent via SMS or exported to a PC.
Target	Proviral DNA and RNA	
Genotypes and/ or subtypes	Group M (A, B, C, D, CRF01_AE, F, G), Group N, Group O and a variety of recombinants including: CRF02_AG, CRF06_cpx, CRF11_cpx, CRF13_cpx, A/AE, D/A and D/F. (Assessed using the 1st WHO International HIV-1 RNA Genotype Panel, Rush University Genotype panels and subtyped clinical samples consisting of samples representing various subtypes and or groups.)	
Type of result	Qualitative, Yes or No result.	
Linear range	Limit of detection: 400 copies/mL of HIV-1 RNA.	
Output	Yes or No result.	
DNA or RNA specific?	Detects both proviral DNA and RNA.	
Polyvalency	Same instrument can be used to run the following assays: 1. SAMBA I HIV-1 Semi-Q test using plasma 2. SAMBA I HIV-1 Qual test using plasma	Same instrument system can be used to run the following assays: 1. SAMBA II HIV-1 Semi-Q Test using plasma Other assays under development: 1. SAMBA II HIV-1 Semi-Q Test using whole blood (Q2 2017) 2. SAMBA II HIV-1 Qual Test using plasma (Q2 2017) 3. SAMBA II Flu A/B Duplex Test (Prototye developed) 4. SAMBA II CT/NG Duplex Test (Prototye developed) 5. SAMBA II HBV Test (R&D) 6. SAMBA II HCV Test (R&D)
	PERFORMANCE	
Sensitivity - analytical and clinical (source)	95.7- 100% (from four independent clinical evaluations in Kenya, Malawi, Nigeria, Uganda and Zimbabwe.)	100% (From clinical specimens from Ukraine, Uganda and Malawi)
Specificity - analytical and clinical (source)	Clinical specificity: 99.2- 100% (from four independent clinical evaluations in Kenya, Malawi, Nigeria, Uganda and Zimbabwe.)	100% (From clinical specimens from Ukraine, Uganda and Malawi)
Bias (source)	N/A	N/A
Intra-assay precision (source)	N/A	N/A
Inter-assay precision (source)	N/A	N/A
	SAMPLE	
Sample preparation (steps)	Whole blood using a capillary-based blood collection system (provided with the kit).	
Sample type	Whole blood (capillary or venous).	

Continued overleaf

Product	SAMBA I HIV-1 QUAL WHOLE BLOOD TEST	SAMBA II HIV-1 QUAL WHOLE BLOOD TEST
SAMPLE		
Sample volume	150µL sample input, assay requires 100µL	
Sample stability	2-30° C for up to 18 hours.	
Nucleic acid extraction method	Semi-automated system with three manual interventions at the sample transfer step from SAMBAprep extraction system to the SAMBAamp amplification detection system.	Automated (sample in - result out system).
Time to result	105 - 120 minutes	
Capacity	Up to six samples per batch for SAMBAprep, up to four samples per batch for SAMBAamp.	1 sample per run
Batching?	Yes	Random access modular system: - Each Tablet module can control up to 4 Assay modules.
Throughput per end-user per hour and/or 8hr day	1 SAMBAprep + 1 SAMBAamp = 16-20 tests/day 1 SAMBAprep + 2 SAMBAamp = 28-32 tests/day 1 SAMBAprep + 3 SAMBAamp = 42-48 tests/day	4 runs/day/assay module giving a flexible throughput of 4-20 tests per day (Number of assay modules can be increased to match the site requirements for throughput)
INSTRUMENT		
Size of device	SAMBAprep: 67 X 64 X 50 cm, SAMBAamp: 41 X 32 X 14 cm	Assay module: 20 x 39 x 34 (cm)
Weight of device	SAMBAprep: 53 kg, SAMBAamp: 3.8 kg	9.9 kgs
Robustness	Suitable for resource-limited settings.	
Environmental requirements	15- 35° C, relative humidity up to 80%	
Power requirements	SAMBAprep: 100 - 250 V, 50 - 60Hz, SAMBAamp: 100 - 250 V, 50 - 60Hz	100 - 250 V, 50 - 60 Hz
Time to battery charge	External battery provided to complete test-run.	
Battery duration (hours)	One run	
Alternative charging options	Solar panel and/or external battery sources.	
Ease of use	SAMBAprep: 4.3 inch back-lit LCD touch panel showing operational status, step-by-step instructions and any system errors. SAMBAamp: Two line alpha-numeric back-lit display screen which reports status, operator instructions and any errors such as temperature.	1. Simple smart device user interface using a Tablet. 2. The results can be sorted by patient name, patient ID, date of test, assay type etc. 3. The tablet module reports system errors. 4. The assay module has a LED strip which indicates instrument status (white = machine available, green = in use and red = system error). 5. External bluetooth printer provided with tablet module. 6. In-built camera for automated results recording.
Display languages	English	
Built-in memory storage capacity	N/A	100,000 test results
Connectivity options	N/A	Via SMS and exportable to PC (Cloud based dashboard under development)
Interpretation of result	Visual results on a test-strip.	Automated camera read out with visual verification step.
Instrument lifespan	5 years	5 years (expected)
Other non-proprietary equipment required	Centrifuge	N/A
Regulatory approval	CE-IVD approved, WHO PQ ongoing.	CE-IVD approved, WHO PQ ongoing.
KIT		
Kit components	**SAMBA I HIV-1 Qual Whole Blood Test (4200-12):** SAMBAmp Cartridge (4200A), Reagent Tube (4200B), SAMBA Detection buffer (4200C), QB Cartridge 1 (4200E), QB Cartridge 2 (4200F), QB Cartridge 3 (4200G), Output Tube (4200H)	QB II Cartridge 1 (4500A), QB II Cartridge 2 (4500B), QB II Cartridge 3 (4500C), QB II Cartridge 4 (4500D).
Kit sizes	12 tests/kit	
Internal control(s)	Each test incorporates an Internal Control, which controls for sample extraction, amplification and detection.	
Compatible with EQA and which?	Externally sources EQA panels including, CDC Proficiency testing panel, Rush University EQA panel, and others.	
Mean time between failures	Proprietary	
Transport and storage	2-37°C for long term storage, -10 - 55°C shipping stability (for 1 month), No cold chain transport required	
Fridge at -80°C required?	Not required	
Shelf life (of each item in the kit)	9 months (ongoing)	

Product	SAMBA I HIV-1 QUAL WHOLE BLOOD TEST	SAMBA II HIV-1 QUAL WHOLE BLOOD TEST
	KIT	
Performance protocol (steps)	The steps are as follows: (1) Sample collection (2) Insert sample and cartridges into SAMBAprep machine (3) Push start button (4) Upon completion of run, place tube containing extracted sample into SAMBAamp (5) Load SAMBAamp cartridge (6) Transfer extracted sample into reagent tube (7) Push start button (8) When beep sounds transfer sample to the SAMBAamp cartridge (9) Amplification cartridge at completion of ampfication step (beep will sound), rotate cartridge manually, plunge detection buffer (10) Read test results visually at end of detection.	(1) Scan test kit on the Tablet module (2) Scan patient tracking card on the Tablet module (3) Load cartridges and sample on the machine (4) Press start (5) Verify and print results
Non-proprietary components required outside of the kit	Blood collection kit comprising of lancet, blood collection (SAFE-T-FILL Mini capillary blood collection tube) and alcohol swab and free size gloves.	
Regulatory approval	CE-IVD approved, WHO-PQ ongoing	
In-country approvals	Approved in Kenya, Zimbabwe and Uganda. Evaluation completed in Malawi and Nigeria.	Approved in Kenya, Zimbabwe and Uganda. Evaluation completed in Malawi.
	USAGE	
Technical skill required	Skilled laboratory technician or laboratory assistant.	No laboratory skills required. Task shifting studies performed on SAMBA II system in Uganda and Zimbabwe have demonstrated that all levels of healthcare workers are able to run the assay proficiently and, upon completion of the training protocol, provide training to fellow workers. Healthcare levels participating in the study ranged from laboratory technologists, laboratory assistants, nurses, midwives, microscopists, nursing assistants and counsellors.
Applicable settings	Near point-of-care, hospitals, clinics, and large healthcare centres with electricity.	True point of care suitable for all levels of a healthcare setting with electricity or provision for solar power.
Laboratory set-up	Hospitals, clinics, and large healthcare centres with electricity.	None except for electricity or provision for solar power.
Waste disposal requirements	Sample tube to be disposed of in infectious waste. All other cartridges can be disposed of in laboratory waste. No toxic waste (Guanidine thiocyanate) disposal requirements.	

	HIV VIRAL LOAD	
Company	**Diagnostics for the Real World, Ltd**	
Product	**SAMBA HIV-1 SEMI-Q TEST**	**SAMBA II HIV-1 SEMI-Q TEST**
	ASSAY	
Intended use (as per regulatory approval)	In vitro nucleic acid-based amplification assay for the semi-quantitative detection of HIV-1. Intended for use as an aid in the monitoring of HIV-1 viral load in patients on antiretroviral therapy. Not intended to be used as a screening test nor as a diagnostic test for HIV-1.	
Principle of the assay	Performing the test is divided into two steps: sample preparation and sample testing (amplification/detection). The first step is the extraction of the target RNA using an automated sample preparation procedure in the SAMBAprep instrument. The procedure lyses the virus and releases the nucleic acid, which is then captured onto a silica membrane in a column. The column with the bound nucleic acid is then washed, followed by elution of the nucleic acid into the Output Tube. The Output Tube is then transferred into the SAMBAamp instrument for the amplification and detection steps. The SAMBAamp cartridge and Reagent Tube are placed into the SAMBAamp instrument. Detection buffer is added to the colour-labeled anti-hapten sphere in the SAMBAamp cartridge. The sample is transferred from the Output Tube to the Reagent Tube, heated, and then transferred to the hermetically sealed SAMBAamp cartridge previously placed in the SAMBAamp instrument. The SAMBAamp cartridge contains all the reagents required to amplify HIV-1 nucleic acids in the SAMBAamp instrument. At the end of the amplification cycle, the Detection Buffer is added to the sample by depressing the plunger on the SAMBAamp cartridge and the amplified sample is then wicked up on the Test Strip by capillary action within the SAMBAamp cartridge, giving a visual readout of the result.	The Test is a fully automated assay run on the SAMBA II instrument system consisting of the SAMBA II Assay Module, and a control unit – the SAMBA II Tablet module. Nucleic acid extraction, amplification of the nucleic acid target and the detection of the amplification products are performed in the SAMBA II Assay Module. The extraction phase of the assay involves the lysis to release nucleic acid (RNA) into solution, which is then captured by a silica membrane column. The bound nucleic acid is washed and eluted from the membrane and the HIV target sequence is amplified in a sealed cartridge. After amplification, a coloured-labeled anti-hapten detection solution is mixed with the amplification product and the mixture is wicked in a Test Strip. The test result (i.e. bluish to purple lines on the Control Line and/or Test Line) is captured by a built-in camera, which is recorded and can be read on the Tablet module. Results are stored and may be printed from the Bluetooth printer. Results can be sent via SMS or exported to a PC.
Target	HIV-1 RNA	

Continued overleaf

Product	SAMBA HIV-1 SEMI Q TEST	SAMBA II HIV-1 SEMI-Q TEST
ASSAY		
Genotypes and/ or subtypes	Group M (A, B, C, D, CRF01_AE, F, G), Group N, Group O and a variety of recombinants including: CRF02_AG, CRF06_cpx, CRF11_cpx, CRF13_cpx, A/AE, D/A and D/F. (Assessed using the 1st WHO International HIV-1 RNA Genotype Panel, Rush University Genotype panels and subtyped clinical samples consisting of samples representing various subtypes and or groups.)	
Type of result	Semi-Quantitative (>/< 1,000 ± 0.3 log copies/mL).	
Linear range	N/A. Cut-off at 1,000 copies/mL (± 0.3 log assay variation).	
Output	Viral load >/< 1,000 ± 0.3 log copies/mL.	
DNA or RNA specific?	RNA	
Polyvalency	Same instrument system can be used to run the following assays: 1. SAMBA I HIV-1 Qual Test using whole blood. 2. SAMBA I HIV-1 Qual Test using plasma.	Same instrument system can be used to run the following assays: 1. SAMBA II HIV-1 Qual Whole Blood Test Other assays under development: 1. SAMBA II HIV-1 Semi-Q Test using whole blood (Q2 2017) 2. SAMBA II HIV-1 Qual Test using plasma (Q2 2017) 3. SAMBA II Flu A/B Duplex Test (Prototye developed) 4. SAMBA II CT/NG Duplex Test (Prototye developed) 5. SAMBA II HBV Test (R&D) 6. SAMBA II HCV Test (R&D)
PERFORMANCE		
Sensitivity - analytical and clinical (source)	Overall concordance: 98%, 94.8%, 95.9%, 96.4% (In independent clinical evaluations performed in Malawi, Uganda, Kenya and Zimbabwe, respectively.). Remarkably and consistently low invalid rate of <0.36% in~ 55,000 samples tested in 6 MSF sites since Aug 2013.	Overall concordance: 98.1% (From evaluation in Uganda)
Specificity - analytical and clinical (source)		
Bias (source)	N/A	
Intra-assay precision (source)	N/A	
Inter-assay precision (source)	N/A	
SAMPLE		
Sample preparation (steps)	Plasma preparation	
Sample type	Plasma	
Sample volume	300 µL (assay requires 200 µL)	
Sample stability	15-30°C for up to 12 hours or at 2-8°C for up to 5 days, or at -20° to -80°C for long-term storage.	
Nucleic acid extraction method	Semi automated system with three manual interventions at the sample transfer step from SAMBAprep extraction system to the SAMBAamp amplification detection system.	Automated (sample in - result out system).
Time to result	75 - 90 minutes	
Capacity	N/A	1 sample per run
Batching?	Yes	Random access modular system: - Each Tablet module can control up to 4 Assay modules.
Throughput per end-user per hour and/or 8hr day	1 SAMBAprep + 1 SAMBAamp = 16 - 20 tests/day 1 SAMBAprep + 2 SAMBAamp = 28 - 32 tests/day 1 SAMBAprep + 3 SAMBAamp = 42 - 48 tests/day	4 runs/day/assay module giving a flexible throughput of 4-20 tests per day (Number of assay modules can be increased tomatch the site requirements for throughput)
INSTRUMENT		
Size of device	SAMBAprep: 67 X 64 X 50 cm, SAMBAamp: 41 X 32 X 14 cm	Assay module: 20 x 39 x 34 (cm)
Weight of device	SAMBAprep: 53 kg, SAMBAamp: 3.8 kg	9.9 kgs
Robustness	Suitable for resource-limited settings.	
Environmental requirements	15 - 35ºC, relative humidity up to 80%	
Power requirements	SAMBAprep: 100 – 250 V, 50-60 Hz, SAMBAamp: 100 – 250 V, 50-60 Hz	100 - 250 V, 50 - 60 Hz
Time to battery charge	External battery provided to complete test-run	
Battery duration (hours)	One run	
Alternative charging options	Solar panel and/or external battery sources	
Ease of use	SAMBAprep: 4.3 inch back-lit LCD touch panel showing operational status, step by step instructions and any system errors. SAMBAamp: Two line alpha-numeric back-lit display screen which reports status, operator instructions and any errors such as temperature.	1. Simple smart device user interface using a Tablet. 2. The results can be sorted by patient name, patient ID, date of test, assay type etc. 3. The tablet module reports system errors. 4. The assay module has a LED strip which indicates instrument status (white = machine available, green = in use and red = system error). 5. External bluetooth printer provided with tablet module. 6. In-built camera for automated results recording.

Product	SAMBA HIV-1 SEMI Q TEST	SAMBA II HIV-1 SEMI-Q TEST
INSTRUMENT		
Display languages	English	
Built-in memory storage capacity	N/A	100,000 test results
Connectivity options	N/A	Via SMS and exportable to PC (Cloud based dashboard under development)
Interpretation of result	Visual results on a test-strip.	Automated camera read out with visual verification step.
Instrument lifespan	5 years	5 years (expected)
Other non-proprietary equipment required	Centrifuge	N/A
Regulatory approval	CE-IVD approved, WHO-PQ ongoing	
KIT		
Kit components	**SAMBA HIV-1 Semi-Q Test (4200-12):** SAMBAmp Cartridge (4100A), Reagent Tube (4100B), SAMBA Detection buffer (4100C), Semi Q Cartridge 1 (4100E), Semi Q Cartridge 2 (4100F), Semi Q Cartridge 3 (4100G), Output Tube (4100H)	SQ Cartridge 1 (4400A), SQ Cartridge 2 (4400B), SQ Cartridge 3 (4400C), SQ Cartridge 4 (4400D).
Kit sizes	12 tests/kit	
Internal control(s)	Each test incorporates an Internal Control, which controls for sample extraction, amplification and detection.	
Compatible with EQA and which?	Externally sources EQA panels including, CDC Proficiency testing panel, Rush University EQA panel, and others	
Mean time between failures	Proprietary	
Transport and storage	2-37°C for long term storage, -10 - 55°C shipping stability (for 1 month), No cold chain transport required	
Fridge at -80°C required?	Not required	
Shelf life (of each item in the kit)	9 months (ongoing)	6 months (ongoing)
Performance protocol (steps)	The steps are as follows: (1) sample collection (2) insert sample and cartridges into SAMBAprep machine (3) push start button (4) upon completion of run, place tube containing extracted sample into SAMBAamp (5) Load SAMBAamp cartridge (6) transfer extracted sample into reagent tube (7) push start button (8) When beep sounds transfer sample to the SAMBAamp cartridge (9) amplification cartridge at completion of ampfication step (beep will sound), rotate cartridge manually, plunge detection buffer (10) Read test results visually at end of detection.	(1) Scan test kit on the Tablet module (2) Scan patient tracking card on the Tablet module (3) Load cartridges and sample on the machine (4) Press start (5) Verify and print results
Non-proprietary components required outside of the kit	Off the shelf Blood collection system, Cenrifuge for plasma separation	Centrifuge
Regulatory approval	CE-IVD approved, WHO-PQ ongoing	
In-country approvals	Approved in Kenya, Malawi, Zimbabwe and Uganda. Evaluation completed in Nigeria.	Approved in Kenya, Zimbabwe and Uganda. Evaluation completed in Malawi.
USAGE		
Technical skill required	Skilled Laboratory technician or laboratory assistant	No laboratory skills required. Task shifting studies performed on SAMBA II system in Uganda and Zimbabwe have demonstrated that all levels of healthcare workers are able to run the assay proficiently and, upon completion of the training protocol, provide training to fellow workers. Healthcare levels participating in the study ranged from laboratory technologists, laboratory assistants, nurses, midwives, microscopists, nursing assistants and counsellors.
Applicable settings	Near point-of care, hospitals, clinics and large healthcare centres with electricity	True point of care suitable for all levels of and healthcare setting with electricity or provision for solar power.
Laboratory set-up	Hospitals, clinics and large healthcare centres with electricity	None except for electricity or provision for solar power.
Waste disposal requirements	Sample tube to be disposed of in infectious waste. All other cartridges can be disposed of in laboratory waste. No toxic waste (Guanidine thiocyanate) disposal requirements.	

Continued overleaf ⋰

02 | PRICING

SAMBA I EARLY INFANT DIAGNOSIS					
Instrument	**Reference number**	**EXW ($)**	**Cartridge/reagents**	**Reference number**	**EXW ($)**
SAMBA I instrument system		$56,000	**SAMBA I HIV-1 Qual Whole Blood Test**	4200-12	$213.60 - $448.80
- SAMBAprep	I19-0005				
- SAMBAamp	I19-0004				
Instrument Accessories	**Reference number**	**EXW ($)**	**Non-proprietary equipment and consumables**	**Reference number**	**EXW ($)**
Uninterrupted power supply	N/A	N/A	Sample collection tube, EDTA	KABE list no. 07 0614, or C13-0001-12	N/A
75 uL Fixed-volume pipette	C12-0001	N/A	Lancet	C12-0005	N/A
100 uL Fixed-volume pipette	C12-0003	N/A	Alcohol swabs	C01-0005	N/A
			ART 1000 Pipet Tips	C01-0002	N/A
			ART 200 Pipet Tips	C01-0003	N/A
Cost per instrument		**$56,000**	**Cost per test result**		**$17.80 - $37.40**

SAMBA I VIRAL LOAD					
Instrument	**Reference number**	**EXW ($)**	**Cartridge/reagents**	**Reference number**	**EXW ($)**
SAMBA I instrument system		$56,000	**SAMBA HIV-1 Semi-Q Test**	4100-12	$213.60 - $448.80
- SAMBAprep	I19-0005				
- SAMBAamp	I19-0004				
Instrument Accessories	**Reference number**	**EXW ($)**	**Non-proprietary equipment and consumables**	**Reference number**	**EXW ($)**
Uninterrupted power supply	N/A	N/A	Sample collection tube, Untreated	KABE list no. 05 3615, C19-0015-12	N/A
75 uL Fixed-volume pipette	C12-0001	N/A	ART 1000 Pipet Tips	C01-0002	N/A
100 uL Fixed-volume pipette	C12-0003	N/A	ART 200 Pipet Tips	C01-0003	N/A
300 uL Fixed-volume pipette	C12-0002	N/A			
Cost per instrument		**$56,000**	**Cost per test result**		**$17.80 - $37.40**

SAMBA II EARLY INFANT DIAGNOSIS					
Instrument	**Reference number**	**EXW ($)**	**Cartridge/reagents**	**Reference number**	**EXW ($)**
SAMBA II instrument system			**SAMBA I HIV-1 Qual Whole Blood Test**	4500-12	$213.60 - $448.80
- SAMBA II Assay Module	I19-0006-AM	$18,000 - $24,000			
- SAMBA II Tablet Module including Bluetooth printer and Secure tablet charging stand, IR key and Programmer	I19-0006-TM	$1,750			
Instrument Accessories	**Reference number**	**EXW ($)**	**Non-proprietary equipment and consumables**	**Reference number**	**EXW ($)**
Uninterrupted power supply	N/A	N/A	Sample collection tube, EDTA	KABE list no. 07 0614, or C13-0001-12	N/A
			Lancet	C12-0005	N/A
			Alcohol swabs	C01-0005	N/A
			SAMBA II Sample Card, QB II	C19-0045	
Cost per instrument		**$18,000 - $24,000**	**Cost per test result**		**$17.80 - $37.40**

SAMBA II HIV VIRAL LOAD					
Instrument	**Reference number**	**EXW ($)**	**Cartridge/reagents**	**Reference number**	**EXW ($)**
SAMBA II instrument system			**SAMBA II HIV-1 Semi-Q Test**	4400-12	$213.60 - $448.80
- SAMBA II Assay Module	**I19-0006-AM**	$18,000 - $24,000			
- SAMBA II Tablet Module including Bluetooth printer and Secure tablet charging stand, IR key and Programmer	**I19-0006-TM**	$1,750			
Instrument Accessories	**Reference number**	**EXW ($)**	**Non-proprietary equipment and consumables**	**Reference number**	**EXW ($)**
Uninterrupted power supply	N/A	N/A	Sample collection tube, untreated	KABE list no. 05 3615, C19-0015-12	N/A
300 uL Fixed-volume pipette	C12-0002	N/A	ART 1000 Pipet Tips	C01-0002	N/A
			SAMBA II Sample Card, SQ	C19-0044	N/A
Cost per instrument		**$18,000 - $24,000**	**Cost per test result**		**$17.80 - $37.40**

03 | TIERED AND VOLUME-BASED PRICING

SAMBA I HIV EARLY INFANT DIAGNOSIS AND VIRAL LOAD

Instrument		**Test kit**	
Volume	**FCA ($)**	**Volume**	**FCA ($)**
1 SAMBAprep + 1 SAMBAamp	$56,000.00	Base - 150,000	$37.40
1 SAMBAprep + 2 SAMBAamp	$65,000.00	150,000 - 300,000	$28.80
1 SAMBAprep + 3 SAMBAamp (recommended configuration for optimal throughput)	$72,000.00	300,000 - 500,000	$24.60
		500,000 - 750,000	$21.60
		750,000 - 1 Million	$19.40
		>1 Million	$17.80

* Volume breakdown based on global volume of procurement, pricing will reduce as global volumes are achieved

SAMBA II HIV EARLY INFANT DIAGNOSIS AND VIRAL LOAD

Instrument		**Test kit**	
Volume	**FCA ($)**	**Volume**	**FCA ($)**
SAMBA II assay module, 1 - 200 units	$24,800.00	Base - 150,000	$37.40
SAMBA II assay module, >200 units	$18,000.00	150,000 - 300,000	$28.80
SAMAB II Table module (controls up to 4 assay module)	$1,750.00	300,000 - 500,000	$24.60
		500,000 - 750,000	$21.60
		750,000 - 1 Million	$19.40
		>1 Million	$17.80

* Volume breakdown based on global volume of procurement, pricing will reduce as global volumes are achieved

04 | MAINTENANCE, WARRANTY & TRAINING

	Description	Cost (US$)
Leasing or reagent rental (RAP)	N/A	N/A
Installation	Simple plug and play installation covered in instrument cost	Included in the price of instrument
Training	Training takes 4-6 hours	Provided free of charge at time of installation
Maintenance	No routine maintenance required by the user	N/A
Length(s) of warranty and additional costs for extended warranty / care plan	Year 1 is covered free of charge under standard warranty, extended warranty is available for procurement to cover Year 2 and 3.	$3,250 per site, per annum for extended warranty
Warranty components	One (1) yearly preventive maintenance service. All parts, labour, repairs and swap-out covered under standard and extended warranty.	N/A
Turnkey option	N/A	N/A
In-country / regional technical support availability	Available via in-country distributor of directly via DRW in-country staff	N/A

05 | CONTACT INFO

Neha Goel
Associate Director
Diagnostics for the Real World

Website: www.drw-ltd.com
Tel: +44 1223 785378
Mobile: +44 7958167621
Email: ng334@cam.ac.uk

SAMBA

SAMBA II

POINT-OF-CARE HCV VL
GENEDRIVE

01 | TECHNICAL AND PERFORMANCE INFORMATION

Company	GENEDRIVE PIC	Product	GENEDRIVE® INSTRUMENT AND GENEDRIVE® HCV ID KIT
ASSAY		**SAMPLE**	
Intended use (as per regulatory approval)	Genedrive HCV ID Kit is an in vitro diagnostic test for the rapid qualitative detection of Hepatitis C Virus (HCV) RNA in human whole blood derived EDTA plasma using the Genedrive instrument. Genedrive HCV ID Kit detects HCV RNA in plasma and is intended for use as an aid in the confirmation of HCV infection. It is intended to aid in the diagnosis of current HCV infection in adult specimens containing HCV genotypes 1-6. Genedrive HCV ID Kit is intended to confirm current HCV infection following a positive HCV antibody test, it is not intended as a screening test to detect the presence of HCV.	**Sample stability**	EDTA Whole blood: 6 hours at room temperature (21.5ºC – 25.4ºC) or 72 hours at 4ºC. EDTA plasma : 24 hours at room temperature (25ºC) or 4 days at 4ºC
		Time to result	90 minutes
		Capacity	Single sample
		Batching?	No
		Throughput per end-user per hour and/or 8hr day	One sample in 90 minutes, 5 samples per 8 hour day
Principle of the assay	The kit utilises proprietary Polymerase Chain Reaction (PCR) technology to amplify and detect HCV RNA within human plasma samples, without the requirement for nucleic acid isolation. Following conversion of viral RNA to DNA and subsequent PCR amplification, the test uses a 91bp region of the HCV 5' untranslated region (UTR) of the genome. PCR end-point melt curve analysis enables the assay to detect whether this HCV viral sequence is present.	**INSTRUMENT**	
		Size of device	12cm x 18cm x 10cm
		Weight of device	600g
		Robustness	Suitable for use in resource limited settings
Target	91bp region of the HCV 5' UTR	**Environmental requirements**	5-50°C, humidity <85% non-condensing
Genotypes and/ or subtypes	1a,1b,2,3,4,5,6	**Power requirements**	Input: 100-240V 1.2A 50/60Hz AC Output: 12 V 8.33A DC
Type of result	Qualitative	**Time to battery charge**	No internal battery
Linear range	N/A	**Battery duration (hours)**	N/A
Output	Detected Positive, Undetected Negative	**Alternative charging options**	Genedrive UPS (available soon)
Polyvalency	Existing: MTB/RIF, Pipeline: HBV	**Ease of use**	Single button operation with easy to follow screen prompts. Minimal user training is required.
PERFORMANCE		**Display languages**	English
Sensitivity - analytical and clinical (source)	99.8% (clinical validation studies)	**Built-in memory storage capacity**	1000 results (12 visible via the instrument screen)
Specificity - analytical and clinical (source)	100% (clinical validation studies)	**Connectivity options**	Genedrive supports the use an external thermal printer for printing of test results. Future expansion of connectivity features for Genedrive are in development.
Bias (source)	N/A	**Interpretation of result**	Platform will display Detected Positive, Undetected Negative, Indeterminate Retest or Control Failed Retest.
Intra-assay precision (source)	N/A		
Inter-assay precision (source)	N/A	**Instrument lifespan**	3 years
SAMPLE		**Other non-proprietary equipment required**	Printer and UPS as required
Sample preparation (steps)	Preparation of plasma		
Sample type	EDTA plasma	**Regulatory approval**	CE-IVD
Sample volume	25µL		

Continued overleaf

Point-of-Care HCV VL – Genedrive continued

KIT		KIT	
Kit components	Each test contains: 1 x Plasma Preparation Cartridge 1 x HCV ID Assay Tube 2 x Cartridge Lid 1 x Nuclease Free Water 1 x Empty Tube	**Non-proprietary components required outside of the kit**	Centrifuge/plasma separation device
Kit sizes	10 tests	**Regulatory approval**	Pending CE-IVD
Internal control(s)	Each test includes an internal process control	**In-country approvals**	Pending
Compatible with EQA and which?	None	**USAGE**	
Mean time between failures	Internal validation studies have demonstrated an efficiency of 96.6%.	**Technical skill required**	Low level skill required
Transport and storage	Transport and storage at 2-28°C	**Applicable settings**	Small and medium sized laboratories, clinics
Fridge at -80°C required?	No	**Laboratory set-up**	Minimal
Shelf life (of each item in the kit)	6 months at launch		
Performance protocol (steps)	1. Dilute plasma 1:2 with nuclease free water 2. Add 15µL to each cartridge channel and attached cartridge lid 3. Insert into instrument and initiate plasma prepation reaction (10 minutes) 4. Once completed, add 100µL nuclease free water to HCV assay tube 5. Remove cartridge lid and add 30µL of HCV assay to each cartridge channel 6. Attach new cartridge lid, insert cartidge into the instrument and initiate HCV assay	**Waste disposal requirements**	As per local requirements

02 | PRICING

Instrument	**Reference number**	**FCA ($)**	**Cartridge/reagents**	**Reference number**	**FCA ($)**
Genedrive® instrument	TBD	$4,000	Genedrive® HCV ID Kit	ID-HCV-03	$25-$30
Instrument Accessories	**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**	**Reference number**	**FCA ($)**
			Dymo LabelWriter 450 (available direct form Dymo)		
			Genedrive UPS		$153
Price per instrument		**$4,153**	**Price per test result**		**$25-$30**

03 | TIERED AND VOLUME-BASED PRICING

Pending finalisation.

04 | MAINTENANCE, WARRANTY & TRAINING

	Description	Cost (US$)
Leasing or reagent rental (RAP)	TBC	
Installation	No installation required	0
Training	2-3 hours of training required Onsite training available Training aids provided	0
Maintenance	No maintenance is required	N/A
Length(s) of warranty and additional costs for extended warranty / care plan	1 year warranty provided, further warranty available to purchase	N/A
Warranty components	Not required	N/A
Turnkey option	Not available	N/A
In-country / regional technical support availability		

05 | CONTACT INFO

Debra Hepburn
Product Marketing Manager
Genedrive

The Incubator Building
48 Grafton Street
Manchester
M13 9XX
United Kingdom

Website: www.genedriveplc.com
Tel: +44(0)7964 270590
Email: D.Hepburn@genedrive.com

Continued overleaf

POINT-OF-CARE HIV VL & HCV VL
MOLBIO DIAGNOSTICS

01 | TECHNICAL AND PERFORMANCE INFORMATION

	HIV VIRAL LOAD	HCV VIRAL LOAD
Company	**Molbio Diagnostics Pvt. Ltd.**	
Product	**TRUELAB/TRUENAT HIV**	**TRUELAB/TRUENAT HCV**
ASSAY		
Intended use (as per regulatory approval)	Chip-based test for the qualitative diagnosis of human HIV-1 and for quantitative estimation of the HIV-1 viral load. The test is intended as an aid in treatment monitoring of patients with HIV-1 infection.	Chip-based test for the diagnosis of HCV and aids in the monitoring of HCV viral load of patients with HCV infection.
Principle of the assay	The HIV-1 and HCV tests works on the principle of Real Time Reverse Transcription Polymerase Chain Reaction (RT-PCR) based on Taqman chemistry. Nucleic Acids from the patient sample is first extracted using Trueprep™AUTO Universal Cartridge Based Sample Prep Device and Trueprep™AUTO Universal Cartridge Based Sample Prep Kit. Six (6) µL of the extracted nucleic acids is then dispensed into a microtube containing freeze-dried PCR reagents, including reverse transcriptase (RT). After allowing approximately 2 minutes for the dried PCR reagents to get hydrated with the extracted nucleic acids, the entire contents is pipetted out and dispensed into the reaction well of the Truenat™ chip. The Truenat™ chip is then inserted in the Truelab™ Real Time micro PCR Analyzer where RNA is first converted into complementary DNA (cDNA) by the RT enzyme and further thermal cycling takes place. A positive amplification causes the dual labeled fluorescent probe in the Truenat™ HIV-1/HCV chip to release the fluorophore in an exponential manner, which is then captured by the built-in opto-electronic sensor and displayed as amplification curve on the analyzer screen, on a real time basis during the test run. In the case of negative samples, amplification does not occur and a horizontal amplification curve is displayed on the screen during the test run. At the end of the test run, "DETECTED" or "NOT DETECTED" result is displayed, and only for plasma samples, in positive cases, quantitative result as copies/ml or IU/mL respectively, is also displayed on the screen. Based on the detection of the internal positive control (IPC), the validity of the test run is also displayed. The IPC is a full process control that undergoes all the processes the specimen undergoes – from extraction to amplification thereby validating the test run from sample to result. Absence of or shift of IPC Ct beyond a pre-set range in case of negative samples invalidates the test run. The results can be printed using the Truelab™ micro PCR printer or transferred to the lab computer/or any remote computer via Wifi network or GPRS/3G network.	
Target	pol gene	5' UTR
Genotypes and/or subtypes	All groups and subtypes of HIV-1	All genotypes and subtypes
Type of result	Qualitative for Whole blood sample Quantitative for plasma samples	Quantitative
Linear range	200 to 10^8 copies per ml	100 to 10^8 IU/ml
Output	Copies/mL	IU/ml
DNA or RNA specific?	DNA and RNA for whole blood RNA for plasma	RNA
Polyvalency	Malaria pf, M. tuberculosis, MTB-RIF, Dengue, Chikungunya, H1N1, HBV quantitative, Salmonella, Chlamydia, Gonorrhea, Trichomonas.	
PERFORMANCE		
Sensitivity - analytical and clinical (source)	TBD	
Specificity - analytical and clinical (source)	>99%	
Bias (source)	TBD	
Intra-assay precision (source)	TBD	
Inter-assay precision (source)	TBD	
SAMPLE		
Sample preparation	Two pipetting steps involved.	
Sample type	Whole Blood for EID. Plasma for viral load.	Whole blood or plasma.
Sample volume	250 µL for whole blood and 500 µL for plasma	
Sample stability	Not provided	
Nucleic acid extraction method	Automated using Trueprep™ Auto Universal Cartridge based sample prep device.	
Time to result	1 hour	

Product	TRUENAT HIV	TRUENAT HCV
SAMPLE		
Capacity	1 sample per run. A 4 sample per run version will be available soon.	
Batching?	No	
Throughput per end-user per hour and/or 8hr day	14 samples / 8hr day (over 50 samples/8hr day with 4 sample version).	
INSTRUMENT		
Size of device	Trueprep™ Auto: 215 x 235 x 115 mm Truelab™ Uno Dx: 248 x 185 x 112 mm	
Weight of device	Trueprep™ Auto: 2.9 kg Truelab™ Uno Dx: 1.5 kg	
Robustness	Rugged, for field use.	
Environmental requirements	Temperature: ≤40°C Relative humidity: ≤80%	
Power requirements	Rechargeable Lithium Ion Battery Pack. Input to AC/DC adaptor: Single Phase 100 – 240V; 50/60Hz; 1500 mA	
Time to battery charge	4 hours	
Battery duration (hours)	Over 8 hours	
Alternative charging options	None	
Ease of use	Very user friendly. All data entry though touch screen. Result available on touch screen, can be printed with Bluetooth printer provided or transmitted wirelessly.	
Display languages	English	
Built-in memory storage capacity	20,000 tests	
Connectivity options	Wi-Fi / GPRS / Bluetooth	
Interpretation of result	"Detected" or "Not Detected" with quantitative value where applicable	
Instrument lifespan	Minimum 5 years	
Other non-proprietary equipment required	None	
Regulatory approval	No, product not yet market launched.	
KIT		
Kit components	Proprietary buffers for sample preparation, disease specific microPCR chips, fixed volume pipettes and filter barrier tips.	
Kit sizes	Packaged for 5 and 20 tests	
Internal control(s)	Full process internal control	
Compatible with EQA and which?	Not provided	
Mean time between failures	Not provided	
Transport and storage	Kit is stable at ≤40°C for 1 month and ≤30°C for one year.	
Fridge at -80°C required?	No	
Shelf life (of each item in the kit)	1 year at room temperature	
Performance protocol	Sample is processed using automated device and extracted nucleic acids are used to perform fully automated PCR on a chip.	
Non-proprietary components required outside of the kit	None	
Regulatory approval	No, product not yet market launched.	
In-country approvals	No, product not yet market launched.	
USAGE		
Technical skill required	Minimally skilled operator.	
Applicable settings	All settings including in the field.	
Laboratory set-up	Any laboratory.	
Waste disposal requirements	Waste to be decontaminated with bleach and disposed as per local regulations and guidelines for medical waste.	

Continued overleaf

02 | PRICING

HIV VIRAL LOAD AND HCV VIRAL LOAD							
Instrument		**Reference number**	**FCA ($)**	**Cartridge/reagents**		**Reference number**	**FCA ($)**
Truelab Real Time micro PCR Workstation	Truelab Uno Dx Real Time micro PCR Analyser	623010001	$12,000	Truenat HIV	Chip-based Real Time PCR test for HIV	N/A (not yet available)	$18
	Trueprep Auto Universal cartridge Based Sample prep Device			Truenat HCV	Chip-based Real Time PCR test for HCV		$18
	Truelab Real Time micro PCR Printer			Trueprep Auto universal sample prep kit	Sample prep kit		$2
	Truepet micropipettes						
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
None				Centrifuge if plasma is used			
				Blood collection kit for capillary blood sample			
				Or sample collection sytem for venipuncture			
Cost per device			**$9,000**	**Cost per test result**			**$20**

03 | TIERED AND VOLUME-BASED PRICING

HIV VIRAL LOAD AND HCV VIRAL LOAD

Instrument		**Test kit**	
Volume	**FCA ($)**	**Volume**	**FCA ($)**
1 instrument	$12,000	1 - 1000 tests	$20
10 instruments	$10,000	1,000 - 10,000 tests 10,000 - 100,000 tests >100,000 tests	$18 $16 $15

04 | MAINTENANCE, WARRANTY & TRAINING

	Description
Leasing or reagent rental (RAP)	Not provided.
Installation	1 – 2 hours
Training	Half day
Maintenance	No specific maintenance
Length(s) of warranty and additional costs for extended warranty / care plan	One year. Annual maintenance contract thereafter.
Warranty components	Parts and labour included
Turnkey option	Not provided.
in-country / regional technical support availability	Will be provided.

05 | CONTACT INFO

N. Sriram
Molbio Diagnostics Pvt. Ltd.

M-46/47, Phase III B, Verna Industrial Estate,
Verna, Goa 403722, India

Website: www.molbiodiagnostics.com
Tel: + 91-832-6682000
Mobile: + 91-9890306689
Email: sales@molbiodiagnostics.com

POINT-OF-CARE HIV EID
NORTHWESTERN GLOBAL HEALTH FOUNDATION

01 | TECHNICAL AND PERFORMANCE INFORMATION

	HIV EARLY INFANT DIAGNOSIS		
Company	**NORTHWESTERN GLOBAL HEALTH FOUNDATION**	**Product**	**LYNX HIV P24 ANTIGEN TEST**
ASSAY		**INSTRUMENT**	
Intended use (as per regulatory approval)	Birth to 18 months, although evaluations still in process in infants less than 4 weeks.	**Size of device**	20.2 x 15.6 x 13.4 cm
Principle of the assay	Qualitative p24 antigen based immunochromatographic assay.	**Weight of device**	1.7 kg
Target	p24 antigen	**Robustness**	Completely enclosed for operation in dusty environments. Comply with EN 60529.
Genotypes and/ or subtypes	HIV-1 (expected to be all subtypes, but still in the process of verifiying).	**Environmental requirements**	15 - 35°C
Type of result	Qualitative	**Power requirements**	Powered by AC mains or 12V DC with internal rechargeable Li-ion battery.
Linear range	N/A	**Time to battery charge**	<1 hour
Output	Control line and/or test line	**Battery duration (hours)**	The platform has a built-in rechargeable battery that lasts up to 8 hours.
DNA or RNA specific?	Neither, p24 antigen.	**Alternative charging options**	No
Polyvalency	None.	**Ease of use**	LYNX has a small screen with a timer which counts down from 11 to 0 (heating step) and from 30 to 0 (strip development step).
PERFORMANCE			
Sensitivity - analytical and clinical (source)	TBD pending external/independent evaluations.	**Display languages**	N/A (none displayed)
Specificity - analytical and clinical (source)		**Built-in memory storage capacity**	None
Bias (source)		**Connectivity options**	Optional reader with connectivity.
Intra-assay precision (source)		**Interpretation of result**	Visually read or interpreted with optional reader.
Inter-assay precision (source)		**Instrument lifespan**	TBD
SAMPLE		**Other non-proprietary equipment required**	No
Sample preparation (steps)	(1) Heel prick (capillary/gravity-based collection device) (2) Dispense blood to LYNX plasma separator; wait 10 minutes (3) Plunge Plasma Collection Pad into the Reaction Tube (4) Separate the Reaction Tube from the LYNX plasma separator	**Regulatory approval**	TBD
		KIT	
		Kit components	TBD
		Kit sizes	10
		Internal control(s)	Yes, control line on strip test.
Sample type	Capillary whole blood.	**Compatible with EQA and which?**	TBD
Sample volume	80µL	**Mean time between failures**	TBD
Sample stability	TBD	**Transport and storage**	No cold chain or humidity control is required for shipping and transport.
Nucleic acid extraction method	N/A	**Fridge at -80°C required?**	No
Time to result	51 minutes	**Shelf life (of each item in the kit)**	Target: 12-18 months at temperatures up to 30 - 40°C and humidity up to 70 - 90%.
Capacity	Instrument will accommodate 1 test at a time.	**Performance protocol (steps)**	(1) Add LYNX buffer into reaction tube and place the reaction tube in the LYNX platform (2) The LYNX will heat the sample (11 minutes) (3) Insert the LYNX test strip (30 minutes) (4) Read the result
Batching?	No		
Throughput per end-user per hour and/or 8hr day	11-12 tests per 8 hr day.		

Continued overleaf

Point-of-Care HIV EID – Northwestern Global Health Foundation continued

KIT		USAGE	
Non-proprietary components required outside of the kit	Phlebotomy consumables (gloves, lancet, alcohol swab, gauze pad).	**Technical skill required**	All staff levels, but feasibility studies are still being done to assess this.
		Applicable settings	For use in sites that perform dried blood spot (DBS) collection or local laboratories.
Regulatory approval	TBD	**Laboratory set-up**	No laboratory required.
In-country approvals	None	**Waste disposal requirements**	Standard biohazardous waste disposal.

02 | PRICING

EARLY INFANT DIAGNOSIS						
Instrument	**Reference number**	**FCA ($)**	**Cartridge/reagents**		**Reference number**	**FCA ($)**
LYNX HIV p24 Antigen Test Processor		$1,000 - 2,000	LYNX HIV p24 Antigen Test	10 tests per kit		$65 - 150
			Blood collection tube (12)			
			LYNX plasma separator (10)			
			LYNX buffer (10)			
			LYNX test strip (10)			
			Package Insert (1)			
			Gloves (20)			
			Lancet (10)			
			Alcohol swab (10)			
			Gauze (10)			
Instrument Accessories	**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
Battery and AC adapter		Included	None			
Cost per device		**$1,000 - 2,000**	**Cost per test result**			**$6.50 - 15**

03 | TIERED AND VOLUME-BASED PRICING

EARLY INFANT DIAGNOSIS (LYNX)

Instrument		**Test kit**	
Volume	**FCA ($)**	**Volume**	**FCA ($)**
100	$900	$25,000	$15
250	$800	$50,000	$10
1,000	$700	$100,000	$9
		$500,000	$6.50

04 | MAINTENANCE, WARRANTY & TRAINING

	EARLY INFANT DIAGNOSIS	
	Description	**Cost (US$)**
Leasing or reagent rental (RAP)	Leasing, capital purchase and reagent rental options anticipated.	
Installation	None required.	N/A
Training	- NWGHF recommends the train-the-trainer model whereby several 'super-users' are selected by the customer to perform further training in the field. - Training materials will be provided by NWGHF for these purposes.	$1,000 per training
Maintenance	None required. Instrument swap during warranty rather than performing on-site service and maintenance.	N/A
Length(s) of warranty and additional costs for extended warranty / care plan	1-2 years; with instrument swap if processor breaks down within the year.	
Warranty components	Local distributor for instrument swap.	
Turnkey option	Total installation package (containing necessary instruments, training, installation and maintenance, as appropriate) is anticipated to be offered.	
In-country / regional technical support availability	Via local distributors.	

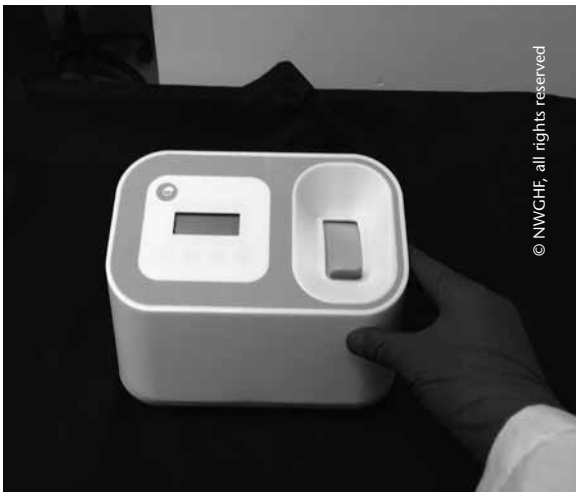
05 | CONTACT INFO

Kara Palamountain
Northwestern Global Health Foundation, President

2232 W Oakdale Ave
Chicago Illinois 60618 USA

Website: www.nwghf.org
Tel: +1 214 207 9485
Mobile: +1 214 207 9485
Email: k-palamountain@nwghf.org

LYNX



POINT-OF-CARE HIV VL
QUIDEL CORPORATION

01 | TECHNICAL AND PERFORMANCE INFORMATION

	HIV VIRAL LOAD Venipuncture Sample Collection	HIV VIRAL LOAD Finger Stick Sample Collection
Company	**QUIDEL CORPORATION**	
Product	**SAVANNA QUANTITATIVE REALTIME HIV-1 ASSAY**	
ASSAY		
Intended use (as per regulatory approval)	Aid in assessing viral response to antiretroviral treatment as measured by changes in HIV-1 RNA levels to (i) identify virological failure; (ii) enable clinicians to provide adherence counseling or (iii) switch failing patients to new drug regimens.	
Principle of the assay	An in vitro reverse transcription-polymerase chain reaction (RT-PCR) assay for the quantitation of HIV-1.	
Target	HIV-1	
Genotypes and/ or subtypes	HIV-1 (all subtypes)	
Type of result	Quantitative	
Linear range	200 - 1,000,000 copies/mL	1,000 - 1,000,000 copies/mL
Output	Copies/mL of HIV-1 in plasma	
DNA or RNA specific?	RNA	
Polyvalency	Multiple molecular infectious disease tests under development.	
PERFORMANCE		
Sensitivity - analytical and clinical (source)	TBD pending external/independent evaluations.	
Specificity - analytical and clinical (source)		
Bias (source)		
Intra-assay precision (source)		
Inter-assay precision (source)		
SAMPLE		
Sample preparation (steps)	(1) Prepare plasma (2) Dispense 200µL of plasma directly into the cartridge	(1) Collect 165µL whole blood (via finger stick) using plasma separator provided in the kit (2) Place the plasma separator into Minifuge for 2-3 minutes (3) Remove plasma separator from device and attach to assay cartridge
Sample type	Plasma	
Sample volume	200µL	165µL of whole blood collected in plasma separator yielding 50µl of plasma.
Sample stability	TBD	
Nucleic acid extraction method	Fully automated.	
Time to result	60 minutes	
Capacity	The instrument is random access and will accommodate 2 tests.	
Batching?	Random access	
Throughput per end-user per hour and/or 8hr day	14 tests per Instrument per 8 hr day.	

	HIV VIRAL LOAD Venipuncture Sample Collection	HIV VIRAL LOAD Finger Stick Sample Collection
INSTRUMENT		
Size of device	W 24 x H 59 x D 62 cm	
Weight of device	<35 kg	
Robustness	Completely enclosed for operation in dusty environments. Comply with EN 60529.	
Environmental requirements	15°C - 40°C	
Power requirements	Powered by AC or DC mains with external battery backup.	
Time to battery charge	TBD	
Battery duration (hours)	Standard: External battery shall complete the cartridges in the instrument. Optional: Expanded external battery capacity.	
Alternative charging options	TBD	
Ease of use	Fully functional and integrated touch screen with no external computer required.	
Display languages	1. English; 2. French; 3. Spanish; 4. Portuguese	
Built-in memory storage capacity	Yes	
Connectivity options	Internal modem or wired data connection. Data can be sent via cellular, data cable or USB.	
Interpretation of result	Standard: Quantitative results based upon copies/mL of plasma or CTs or International Units. Optional: Qualitative copies/mL of plasma based upon a user-defined cutoff.	
Instrument lifespan	TBD	
Other non-proprietary equipment required	Centrifuge	No
Regulatory approval	- Quidel has ISO 13485 Certification. Expect to get WHO PQ approval by 2019	
KIT		
Kit components	Cartridge	Cartridge, lancet, plasma separator device
Kit sizes	Multiple	
Internal control(s)	Internal controls will verify proper conditions and assay performance for amplification.	
Compatible with EQA and which?	Cartridge is combatible with Virology Quality Assurance (VQA) and UK National External Quality Assessment Service (NEQAS).	
Mean time between failures	Target: 10,000 tests per module.	
Transport and storage	No cold chain or humidity control is required for shipping and transport.	
Fridge at -80°C required?	No	
Shelf life (of each item in the kit)	Target: 12-18 months at temperatures up to 30 - 40°C and humidity up to 90%.	
Performance protocol (steps)	(1) Scan assay cartridge on Savanna (2) Scan or enter patient/sample data on Savanna (3) Load cartridge on Savanna (4) Read results on Savanna	
Non-proprietary components required outside of the kit	Phlebotomy consumables (gloves, lancet if finger/needle plus EDTA Vacutainer, alcohol swab, gauze pad).	
Regulatory approval	- Quidel has ISO 13485 Certification - Expect to get WHO PQ approval by 2019	
In-country approvals	None	
USAGE		
Technical skill required	All staff levels in applicable settings.	
Applicable settings	ART clinics, clinics, hospitals.	
Laboratory set-up	Centrifuge required to separate whole blood into plasma.	No laboratory required.
Waste disposal requirements	Standard biohazardous waste disposal.	

Continued overleaf ⋰

Point-of-Care HIV VL – Quidel Corporation continued

02 | PRICING

HIV VIRAL LOAD					
Instrument	**Reference number**	**FCA ($)**	**Cartridge/reagents**	**Reference number**	**FCA ($)**
Savanna Molecular Analyzer	TBD	~$12,000	Savanna HIV Quantitative HIV VL Assay	TBD	~$11
Instrument Accessories	**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**	**Reference number**	**FCA ($)**
Mini-spinner for processing of finger stick specimens	TBD	Included with Savanna Analyzer	Phlebotomy consumables; centrifuge for plasma preparation from venipuncture specimens	N/A	N/A

03 | TIERED AND VOLUME-BASED PRICING

HIV VIRAL LOAD (SAVANNA)

Tiered pricing based on volume TBD.

04 | MAINTENANCE, WARRANTY & TRAINING

	HIV VIRAL LOAD	
	Description	**Cost (US$)**
Leasing or reagent rental (RAP)	Leasing, capital purchase and reagent rental options anticipated.	TBD
Installation	None required.	N/A
Training	TBD	
Maintenance	No routine preventive maintenance anticipated.	
Length(s) of warranty and additional costs for extended warranty / care plan	1-2 years	TBD
Warranty components	Local distributor for instrument swap.	
Turnkey option	Total installation package (containing necessary instruments, training, installation and maintenance, as appropriate) is anticipated to be offered.	TBD
In-country / regional technical support availability	Via local distributors.	

05 | CONTACT INFO

Bill Ferenczy
Senior Director and General Manager,
Savanna Quidel Corporation

12544 High Bluff Drive, Suite 200,
San Diego, CA 92130 USA

Website: www.quidel.com
Tel: +1 619 417 4484
Mobile: +1 619 417 4484
Email: bferenczy@quidel.com

Savanna

LAB-BASED HCV CORE ANTIGEN
ABBOTT (ARCHITECT)

01 | TECHNICAL AND PERFORMANCE INFORMATION

Company	ABBOTT	Product	ARCHITECT HCV AG
ASSAY		**SAMPLE**	
Intended use (as per regulatory approval)	Quantitative determination of HCV core antigen.	**Sample preparation (steps)**	(1) Mix thawed specimens thoroughly by low speed vortexing or by inverting 10 times. Visually inspect the specimens. If layering or stratification is observed, continue mixing until specimens are visibly homogeneous. (2) To ensure consistency in results, specimens must be transferred to a centrifuge tube and centrifuged at 3000 x g for 10 minutes before testing if: • they contain fibrin, red blood cells, or other particulate matter, • they require repeat testing, or • they were frozen and thawed. (3) Transfer clarified specimen to a sample cup or secondary tube for testing. (4) Centrifuged specimens with a lipid layer on the top must be transferred to a sample cup or secondary tube. Care must be taken to transfer only the clarified specimen without the lipemic material.
Principle of the assay	Two-step immunoassay using Chemiluminescent Microparticle Immunoassay (CMIA) technology (with flexible assay protocols, referred to as Chemiflex)		
Type of result	Quantitative		
Linear range	0.00 - 20,000.00		
Output	Result concentration units: fmol/L A 4 Parameter Logistic Curve fit (4PLC, Y-weighted) data reduction method is used to generate a calibration curve Interpretation of Results: • Specimens with concentration values <3.00 fmol/L are considered nonreactive for HCV Ag • Specimens with concentration values ≥3.00 fmol/L are considered reactive for HCV Ag • Specimens with concentration values ≥3.00 fmol/L to <10.00 fmol/L should be retested in duplicate	**Sample type**	Human serum (including serum collected in serum separator tubes), human plasma (collected in Sodium EDTA, Potassium EDTA, Lithium Heparin, Sodium Heparin, Sodium Citrate, or CPD).
Polyvalency	ARCHITECT anti-HCV among others: https://www.abbottdiagnostics.com/en-us/products/ARCHITECT-i2000SR.html#test-menu	**Sample volume**	The minimum sample volume for a single test is 158µL Each Additional Test requires 108µL
PERFORMANCE		**Sample stability**	Specimens may be stored on or off the clot, red blood cells, or separator gel for up to 5 days, refrigerated at 2-8°C. • If testing will be delayed more than 5 days, remove serum or plasma from the clot, red blood cells, or separator gel and store frozen at -20°C or colder. • Avoid more than two freeze/thaw cycles. • Specimens may be shipped at 2-8°C (wet ice), or -20°C or colder (dry ice).
Sensitivity (source)	≤3.00 fmol/L [A total of 452 serum and plasma specimens known to be positive for HCV RNA including genotypes 1a, 1b, 2a, 2b, 3a, 3k, 4a, 5a, 6a, and 6i, were tested. Of the 452 specimens, 97.8% (442/452) were reactive. Seroconversion: sensitivity was evaluated utilizing 10 commercially available panels of sequential specimens from patients who seroconverted for the detection of anti-HCV antibodies. In each panel, a positive result was obtained prior to detection of anti-HCV antibody, resulting in an average reduction between the times of infection and detection of 35.8 days. (package insert)]	**Time to result**	Time to the 1st result: 36 minutes
		Capacity	100 tests/hour
		Batching	Yes
		Throughput	100 tests/hour
Specificity (source)	≥99.5% [In a study where specimens from a blood donor population, hospitalized patients and specimens containing potentially interfering substances were tested. This study includes the specimens from individuals with medical conditions unrelated to HCV infection. A total of 5027 serum and plasma specimens from blood donors were evaluated. (package insert)]	**INSTRUMENT**	
		Size of device	i1000SR: 125.1 H x 149.9 W x 76.2cm D i2000SR: 121.9 H x 154.9 W x 124.5cm D
		Weight of device	i1000SR: 288kg i2000SR: 490.3kg
		Environmental requirements	Water requirements: Type II or better, to dilute buffer concentrate
Intra-assay precision (source)	<10% total CV (package insert)	**Power requirements**	i1000: AC 110-240V ±10%, 47-63 Hz i2000: AC 180-264V, 47-63 Hz
		Regulatory approval	CE Marked, available in 150+ countries

Continued overleaf

Lab-based HCV Core Antigen – Abbott (Architect) continued

Company	ABBOTT	Product	ARCHITECT HCV AG
KIT		**KIT**	
Kit components	Reagents: 6L47 (Microparticles, Conjugate, Assay specific diluent, Pre-treatment reagent 1 and 2, Specimen diluent) Controls: 6L47-10, -11 Calibrators: 6L47-01, -02 Assay CD-ROM: 8K30	**Non-proprietary components required outside of the kit**	Materials required but not provided outside the 6L47 HCV Ag Reagent kit: • ARCHITECT i System • ARCHITECT i System e-Assay CD-ROM (found on www.abbottdiagnostics.com) • 6L47-02 ARCHITECT HCV Ag Calibrators • 6L47-11 ARCHITECT HCV Ag Controls • ARCHITECT i Pre-trigger solutions, trigger solutions, Wash buffer, Reaction vessels, sample cups, septum, replacement cups • Pipettes or pipette tips (optional)
Kit sizes	100 tests		
Internal control(s)	3 Bottles (8 mL each) of ARCHITECT HCV Ag Controls (Negative, Positive 1 and 2)	**Regulatory approval**	CE Marked
Transport and storage	The ARCHITECT HCV Ag Reagent Kit is shipped on dry ice and must be stored at 2-8°C in an upright position after receipt. • When stored and handled as directed, reagents are stable until the expiration date. • The ARCHITECT HCV Ag Reagent Kit may be stored on board the ARCHITECT i System for a maximum of 30 days. After 30 days, the reagent kit must be discarded. For information on tracking onboard time, refer to the ARCHITECT System Operations Manual, Section 5. • Reagents may be stored on or off the ARCHITECT i System. If reagents are removed from the system, store them at 2-8°C (with septums and replacement caps) in an upright position.	**In-country approvals**	Available in all countries that accept a CE-mark and in countries that require registration (approx. 60 countries, excluding the USA and China)
		USAGE	
		Technical skill required	Medium to highly trained lab personel
		Applicable settings	From low- to highly-resourced settings
		Laboratory set-up	Two dedicated areas are recommended: Sample Preparation Area and Instruments Run Area
Refridgeration at -80°C required?	No		
Shelf life (of each item in the kit)	Shelf life upon manufacture: 12 months	**Waste disposal requirements**	According to the regulations of each country
Performance protocol (steps)	2		

02 | PRICING

Instrument		Reference number	FCA ($)
Abbott ARCHITECT i2000SR	Immunoassay Analyser	03M74-02	
Abbott ARCHITECT i2000SR	Stand Alone Base RSH Kit (60 carriers, 8 RSH trays), Two-toned colour	02J47-12	

Cartridge/reagents		Reference number	FCA ($)
ARCHITECT HCV Ag Reagent Kit	100 tests/kit	6L47	
ARCHITECT HCV Ag Calibrators	Calibrators A-F (6 x 4mL)	6L47-02	
ARCHITECT HCV Ag Controls	Negative (1 x 8mL) Control 1 (1 x 8mL) Control 2 (1 x 8mL)	6L47-11	

Instrument Accessories		Reference number	FCA ($)
ARCHITECT i Pre-Trigger Solution	4 x 975 mL	06E23-65	
ARCHITECT i Trigger Solution	4 x 975 mL	06C55-60	
ARCHITECT i Wash Buffer	4 x 975 mL	06C54-58	
ARCHITECT i Wash Buffer (for use with ARCHITECT iARM (Automated Reconstitution Module))	1 x 9.75 L	06C54-88	
ARCHITECT i Reaction Vessels	2000/box 4000/box	07C15-01 07C15-02	
ARCHITECT i Sample Cups	1000/box	07C14-01	
ARCHITECT i Septum	200/box	04D18	
ARCHITECT i Replacement Caps	100/box	04D19-01	

Non-proprietary equipment and consumables		Reference number	FCA ($)
Pipettes			
Pipette tips			

Cost per instrument	Not provided	Cost per test result	$25 - $50
		Cost per person (test result plus instrumentation and other materials)	$200

03 | TIERED AND VOLUME-BASED PRICING

Volume based pricing is determined at a local level. Please contact the local Abbott Representative for additional details.

04 | MAINTENANCE, WARRANTY & TRAINING

	Description
Installation	Provided: installation performed by Abbott service engineer or distributor service engineer certified by Abbott following internal SOP. Prior to installation the Abbott field service representative ensures the site is prepared. The location must meet environmental specifications and electrical requirements before the system can be installed.
Training	Comprehensive Integration: • Validation Expertise, • Certified Training. Training can be done on customer sites or in ADD Commercial Trainings centres. If you have any questions regarding your ARCHITECT System, please contact the local representative or find country-specific contact information on www.abbottdiagnostics.com.
Maintenance (including instrument swap)	Proper maintenance of the ARCHITECT System is important. These suggestions, which are especially useful for integrated and multi-module systems, are provided to help determine efficient strategies for performing maintenance procedures and reducing downtime. When scheduling and performing maintenance procedures: • Schedule maintenance procedures during times of slower workflow. • Verify adequate supplies are on board the system, or available to load, prior to initiating a maintenance procedure. • Perform procedures within the weekly, monthly, and quarterly maintenance categories on different shifts or days. To avoid having these procedures scheduled for the same day, perform some of them early to stagger the schedule.
Length(s) of warranty and additional costs for extended warranty / care plan	Generally a warranty is provided, depending on the country and contract details
Turnkey option	No
In-country / regional technical support availability	Yes, please contact the local representative or find country-specific contact information on www.abbottdiagnostics.com. Remote Diagnostics: AbbottLink system

05 | CONTACT INFO

Julia Koloskova
Abbott Diagnostics, Global Marketing, Sr. Product Manager

Abbott Laboratories, 100 Abbott Park Road
Abbott Park, IL USA 60064

Website: abbottdiagnostics.com
Tel: +1-224-668-3030
Email: julia.koloskova@abbott.com

LAB-BASED HIV EID, HIV VL, HCV VL, HCV GT
ABBOTT (REALTIME)

01 | TECHNICAL AND PERFORMANCE INFORMATION

	HIV EID	HIV VIRAL LOAD	HCV VIRAL LOAD	HCV GENOTYPING
Company	**Abbott**			
Product	**ABBOTT REALTIME HIV-1 QUALITATIVE CE**	**ABBOTT REALTIME HIV-1 CE**	**ABBOTT REALTIME HCV CE**	**ABBOTT REALTIME HCV GENOTYPE II CE**
ASSAY				
Intended use	Qualitative detection of HIV-1 nucleic acids. The test is intended to be used as an aid in the diagnosis of HIV-1 infection in paediatric and adult subjects. The test is not intended to be used as a donor screening test for HIV-1.	Quantitation of HIV-1 for use in conjunction with clinical presentation and other laboratory markers as an indicator of disease prognosis and for use as an aid in assessing viral response to antiretroviral treatment as measured by changes in HIV-1 RNA levels. This assay is not intended to be used as a screening test for HIV-1 or as a diagnostic test to confirm the presence of HIV-1 infection. (2G31-10 package insert)	Quantitation of HCV RNA. The assay is intended for use as an aid in the management of HCV-infected patients undergoing antiviral therapy. The assay is not for screening blood, plasma, serum or tissue donors for HCV, or to be used as a diagnostic test to confirm the presence of HCV infection.	Intended for determining the genotype(s) of HCV. The assay is not for screening blood, plasma, serum or tissue donors for HCV, or to be used as a diagnostic test to confirm the presence of HCV infection in donated blood, plasma, serum or tissue.
Principle of the assay	Real time PCR for the in vitro amplification of HIV-1 nucleic acids.	Real time RT-PCR for the in vitro quantitation of HIV-1.	Real time PCR for the in vitro quantitation of HCV.	Real time PCR for the genotyping of HCV.
Target	HIV-1 RNA polymerase	HIV-1 RNA polymerase	5' UTR of HCV genome	5' UTR for GT 1-6, NS5b for subtypes 1a, 1b
Genotypes and/ or subtypes	Group M (subtypes A, B, C, D, CRF01-AE, F, CRF02-AG, G and H), Group O and Group N.	Group M (subtypes A, B, C, D, CRF01-AE, F, CRF02-AG, G, and H), Group O, and Group N. In addition publications are available regarding the detection of other subtypes and group P (1).	Genotypes 1-6	Genotypes 1, 1a, 1b, and 2 - 6
Type of result	Qualitative	Quantitative	Quantitative	Qualitative
Linear range	N/A	LoD-10,000,000 copies/ml	12 IU/mL (1.08 log IU/mL) to 100 million IU/mL (8.0 log IU/mL) for 0.5mL sample volume	N/A
Output	"HIV-1 Detected" or "Not Detected".	Assay results can be reported in Copies/mL, Log [Copies/mL], International Units (IU)/mL, or Log [IU/mL]	Assay results can be reported in IU/mL or Log IU/mL	Qualitative result
DNA or RNA specific?	Total Nucleic Acid (TNA) extraction	RNA selective extraction	RNA selective extraction	RNA selective extraction
Polyvalency	CE-marked: HIV-1 viral load, HIV-1 qualitative, HCV, HCV GT, HBV, HPV, CT/NG, CMV, EBV, MTB detection; MTB RIF/INH resistance; Zika assay RUO is available outside US Resistance			
PERFORMANCE				
Sensitivity - analytical and clinical (source)	LOD: 110 copies/mL in plasma and 2,500 copies/ mL in whole blood using the DBS procedure (package insert)	LOD: 40 copies/mL for 1.0mL sample volume 40 copies/mL for 0.6mL sample volume 75 copies/mL for 0.5mL sample volume 150 copies/mL for 0.2mL sample volume 839 copies/ml for DBS (package insert)	LOD: 12 IU/mL for 0.5mL sample volume and 30 IU/mL for 0.2mL sample volume (package insert)	LOD: 500 IU/mL (package insert)

Product	ABBOTT REALTIME HIV-1 QUALITATIVE CE	ABBOTT REALTIME HIV-1 CE	ABBOTT REALTIME HCV CE	ABBOTT REALTIME HCV GENOTYPE II CE
Specificity - analytical and clinical (source)	HIV-1 was not detected for 550 out of 550 seronegative samples in both specimen types, resulting in 100.0% specificity (95% CI 99.33 – 100.00%) for both the plasma and DBS assay procedures in a representative study (package insert).	HIV-1 RNA was not detected, resulting in 100% (187/187) specificity (95% CI 98.05 - 100.00) in a representative study, DBS ≥99.5% (package insert).	The specificity of the Abbott RealTime HCV assay was evaluated by analyzing 760 unique HCV negative specimens; 380 plasma specimens and 380 serum specimens. HCV RNA was detected in two of the specimens tested. The observed specificity for this study was 99.74% (758/760) (95% CI 99.05 to 99.97%). (package insert)	100% specificity with 95%CI (package insert)
Bias (source)	N/A	Quantification of the 1st WHO reference panel for HIV-1 genotypes demonstrated bias of <0.5 log copies/mL for (A,B,C,D,AE,F,G,AG-GH,N) (Shutten et al 2007).	The bias observed for each dilution of the 2nd WHO IS ranged from -0.17 to 0.03 log IU/mL (package insert).	N/A
Intra-assay precision (source)	N/A	Not provided	Not provided	N/A
Inter-assay precision (source)	N/A	≤0.19 log copies/mL for plasma & ≤0.29 log copies/mL for DBS (package insert)	≤0.25 log IU/mL (package insert)	N/A
SAMPLE				
Sample preparation	Steps include vortexing (internal control, calibrators if applicable, controls and specimens), pipetting, centrifuge, etc. Once all required consumables, reagents and samples are placed in the *m*2000*sp* or *m*24*sp* (if applicable), each process is walk away (extraction and mastermix addition).			
Sample type	Plasma, DBS		Serum or plasma	
Sample volume	Plasma: 0.2mL DBS: 2 spots of 50µL whole blood each	Plasma: 0.2 mL, 0.5 mL, 0.6 mL, 1.0 ml DBS: 1 spot 70µl whole blood	0.5 mL, 0.2 mL	0.5 mL
Sample stability	Freshly drawn specimens (whole blood) may be held at 15-30°C for ≤6 hours or at 2-8°C for ≤24 hours, prior to preparing plasma specimens through centrifugation or reparing DBS specimens. Plasma: Plasma specimens may be stored at 15-30°C for ≤24 hours or at 2-8°C for ≤5 days. If longer storage is required, plasma specimens may be stored at -10 to -30°C for ≤30 days, or at -70°C or lower. Once thawed, if plasma specimens are not being processed immediately, they can be stored at 2-8°C for ≤6 hours. DBS: Freshly drawn specimens (whole blood) may be held at 15-30°C for ≤6 hours or at 2-8°C for ≤24 hours. DBS on cards may be stored at 15-30°C for ≤12 weeks. Alternatively, cards may be stored at 2-8°C or -10°C or colder for ≤12 weeks.	Freshly drawn whole blood (ACD-A and EDTA) may be held at 15 to 30°C for up to 24 hours or at 2 to 8°C for up to 48 hours prior to processing. Plasma: After plasma preparation, plasma may be stored at 15 to 30°C for up to 24 hours or at 2 to 8°C for up to 5 days. If longer storage is required, plasma specimens must be kept at –70°C or colder. Multiple freeze-thaw cycles should be avoided. If frozen, thaw plasma specimens at 15 to 30°C or at 2 to 8°C. Once thawed, if plasma specimens are not being processed immediately, they can be stored at 2 to 8°C for up to 6 hours. DBS: The cards can be stored under ambient conditions for up to 8 weeks. Under conditions of high humidity (85%), the cards can be stored under ambient temperature for up to 2 weeks. Alternatively, cards can be stored at 2 to 8°C or –10°C or colder for up to 12 weeks. See package insert for details	Freshly drawn whole blood can be held at 2–30°C for up to 6 hours. After centrifugation, serum or plasma can be stored at 15–30°C for ≤24 hours, at 2–8°C for ≤3 days, at -25 to -15°C for ≤60 days, and at -70°C for ≤60 days. See package insert for details	Freshly drawn whole blood can be held at 2–30°C for up to 6 hours. After centrifugation, serum or plasma can be stored at 15–30°C for ≤24 hours, at 2–8°C for ≤3 days, at -25 to -15°C for ≤60 days and at -70°C for ≤60 days. See package insert for details
Nucleic acid extraction method	Manual and automated extraction.	Manual and automated extraction for plasma. Automated extraction for DBS	Manual and automated extraction	Automated extraction
Time to result	5.4 - 7.7 hours	5.4 - 7.6 hours		5.25 hours
Capacity	1 - 96 samples/run including 2 controls	1 - 96 samples/run including 3 controls		24 samples/run including 2 controls
Batching?	Yes	Yes, flexible sample input with mPLUS available		Yes
Throughput per end-user per hour and/or 8hr day	96 samples per 8h day 192 samples per 12h day			48 samples per 8hr day

Continued overleaf

Lab-based HIV EID, HIV VL, HCV VL – Abbott (RealTime) continued

Product	ABBOTT REALTIME HIV-1 QUALITATIVE CE	ABBOTT REALTIME HIV-1 CE	ABBOTT REALTIME HCV CE	ABBOTT REALTIME HCV GENOTYPE II CE
INSTRUMENT				
Size of device	*m*2000*sp*: 179 cm L x 187 cm H x 124.4 cm D *m*24*sp*: 88.1 cm L x 75.9 cm H x 69.6 cm D (not available for HIV-1 Qualitative) *m*2000*rt*: 34 cm L x 49 cm H x 45 cm D			
Weight of device	*m*2000*sp*: 326.8 kg instrument and cabinet *m*24*sp*: 84kg (not available for HIV-1 Qualitative) *m*2000*rt*: 34.1kg			
Robustness	Calls Per Year (CPY) metric, which is ~1.2 CPY for the *m*2000*sp*; 0.42 CPY for the *m*2000*rt*; and 0.6 CPY for the *m*24*sp*.			
Environmental requirements	**Sample Prep:** Operation Temperature: 15-30°C Operation Humidity: 30-80% relative (non-condensing) at ≤30°C Pollution Degree: 2 Operating Altitude: Max 3,000 m Heat: 4,100 BTU/1200 Wh External Light: <8,000 lux (direct sunlight can interfere with the PosID) **Real Time PCR:** Operation Temperature: 15-30°C Maximum change of less than 15°C per 24 hours Operation Humidity: 30-80% relative (non-condensing) Pollution Degree: 2 and only be installed in an environment that has non-conductive pollutants Operating Altitude: Max 3,000 m Heat: 4,100 BTU/1,200 Wh; meets Class B emission limits			
Power requirements	100-240 V			
Time to battery charge	GE UPS (Uninterruptable Power Supply) specified; depends on how long it will take to be charged when attached to the system.			
Battery duration (hours)	GE (General Electric) unit to last at least 20 minutes.			
Alternative charging options	No, lab mains power only			
Ease of use	High ease of use: data station, keypad, mouse, printer, and bar code scanner.			
Display languages	*m*2000: English, French, Spanish, Italian, German, Portuguese, Russian, and Chinese *m*24: English (not available for HIV-1 Qualitative)			
Built-in memory storage capacity	2 MB			
Connectivity options	Yes, connectivity via Laboratory Information Systems available and interface to mobile system in development; AbbottLink available.			
Interpretation of result	Qualitative: "HIV-1 Detected" or "Not Detected".	"Target not detected", "Detected", viral load provided if within linear range or ">ULQ".		Qualitative result
Instrument lifespan	*m*2000 System planned to be available at least until 2025			
Other non-proprietary equipment required	Centrifuge, vortex mixer. In addition for manual extraction: dry heating blocks' for DBS: 15.8 mm well diameter heat block (to fit 15 mm diameter Master Mix Tubes)			
Regulatory approval	CE-marked, WHO-prequalification with assay	HIV-1 viral load with plasma sample type: CE, FDA, WHO Prequalification with assay HIV-1 viral load with plasma and DBS sample type: CE-marked; WHO Prequalification with assay	CE-marked, FDA approved	
KIT				
Kit components	1. DNA Extraction kit: Lysis Buffer, Wash 1 and Wash 2, Microparticles and Elution Buffer 2. Amplification kit: amplification reagent pack and internal control 3. Control kit: 12 vials negative control, 12 vials positive control 4. DBS buffer for HIV-1 qualitative (if applicable)	1. RNA Extraction kit: Lysis Buffer, Wash 1 and Wash 2, Microparticles and Elution Buffer 2. Amplification kit: amplification reagent pack and internal control 3. Control kit: 8 vials negative control, 8 vials high positive control, 8 vials low positive control 4. Calibrator kit: 12 vials cal A and 12 vials cal B 5. DBS buffer for HIV-1 viral load (if applicable)	1. RNA Extraction kit: Lysis Buffer, Wash 1 and Wash 2, Microparticles and Elution Buffer 2. Amplification kit: amplification reagent pack and internal control 3. Control kit: 8 vials negative control, 8 vials high positive control, 8 vials low positive control 4. Calibrator kit: 12 vials cal A and 12 vials cal B 5. DBS buffer for HIV-1 viral load (if applicable)	RNA Extraction kit: Lysis Buffer, Wash 1 and Wash 2, Microparticles and Elution Buffer Amplification kit: amplification reagent pack and internal control Control kit: 4 vials negative control, 4 vials positive control
Kit sizes	Extraction: 96 tests (4 x 24 tests/pack) Amplification: 96 tests (4 x 24 tests/pack)			Extraction: 96 tests (4 x 24 tests/pack) Amplification: 24 tests (1 x 24 tests/pack)
Internal control(s)	Yes; processed through sample extraction until detection with each sample.			
Compatible with EQA and which?	Amenable to EQA			
Mean time between failures	191 days/ 1.91 Calls per Year for *m*2000system			

Product	ABBOTT REALTIME HIV-1 QUALITATIVE CE	ABBOTT REALTIME HIV-1 CE	ABBOTT REALTIME HCV CE	ABBOTT REALTIME HCV GENOTYPE II CE
KIT				
Transport and storage	Amplification reagents and controls transported on dry ice and stored at -10°C or colder; sample preparation reagents stored at 15°C to 30°C	Amplification reagents transported on dry ice and stored at -25°C to -15°C; Calibrators and controls transported on dry ice and stored at -10°C or colder; Sample preparation reagents store at 15° C to 30°C	Amplification reagents, calibrators and controls transported on dry ice and stored at -10°C or colder; sample preparation reagents store at 15° C to 30°C	Amplification reagents and controls transported on dry ice and stored at -25°C to -15°C; sample preparation reagents stored at 15-30°C
Fridge at -80°C required?	Not for reagents			
Shelf life (of each item in the kit)	Shelf life upon manufacture: 18 months			
Performance protocol	Three automated steps: 1. Extraction of the nucleic acid 2. Mastermix preparation and addition: preparation of the mastermix by combining the individual amplification reagent components and addition of the prepared mastermix to aliquots of the extracted nucleic acid samples in order to set up PCR plate 3. Amplification and Detection: Simultaneous amplification and detection of the target sequences (e.g. HIV-1 and internal control) on a cycle by cycle.			
Non-proprietary components required outside of the kit	Yes, see package insert for details (e.g. pipette tips)			
Regulatory approval	CE, WHO-prequalification with assay	HIV-1 viral load with plasma sample type: CE, FDA, WHO Prequalification with assay HIV-1 viral load with plasma and DBS sample type: CE-marked; WHO Prequalification with assay	CE-marked, FDA approved	
In-country approvals	CE, WHO-prequalification with assay	Abbott RealTime HIV-1(plasma sample type) available globally. Abbott RealTime HIV-1 (plasma and DBS sample type) available in countries accepting CE-mark.	Abbott RealTime HCV available globally.	Abbott RealTime HCV GT available globally.
USAGE				
Technical skill required	Medium-highly trained; precision pipetting required at low volumes			
Applicable settings	From low- resource to highly-resourced settings			
Laboratory set-up	Two dedicated areas, Sample Preparation Area and Amplification Area, are recommended when the Abbott *m*2000*sp* and Abbott *m*2000*rt* are used			
Waste disposal requirements	According to the regulations of each country.			

02 | PRICING

HIV EARLY INFANT DIAGNOSIS

Instrument		Reference number	FCA ($)	Cartridge/reagents		Reference number
*m*2000*sp*	Sample Extraction, up to 96 samples	09K14-002	$170,000*	*m*Sample Preparation Systems DNA (4x24 Preps)	Sample preparation, extraction reagent	06K12-024
*m*2000*rt*	Amplification and detection	09K15-001		Abbott RealTime HIV-1 Qualitative Amplification Reagent Kit CE	1 kit (96 tests; 4 x 24 tests/pack)	04N66-090
				Abbott RealTime HIV-1 Qualitative Control Kit CE	1 kit (2 levels with 12 replicates per level)	04N66-080
				Abbott RealTime HIV-1 Qualitative Amplification Including Uracil-N-Glycosylase (UNG) optional	1 tube, 112 µL, 1U/µL	04N66-066
				*m*Sample Preparation System RNA Bulk Lysis Buffer (for DBS procedure)	3 x 70 ml	02N77-001

Instrument Accessories		Reference number	FCA ($)	Non-proprietary equipment and consumables	FCA ($)
Abbott RealTime HIV-1 Qualitative *m*2000 Combined Application CD-ROM		04N66-001 or higher		None	
Manual sample preparation startup kit Startup kit for manual sample prep (cooler, 2 magnetic stands)		02N28-001			
Disposable Tips (DiTis): 1mL (2304 Tips)		04J71-010			
Disposable Tips (DiTis): 200µL (2304 Tips)		04J71-017			
5mL Reaction Vessels (2000 Vessels)		04J71-020			
200 mL Reagent Vessels (90 Vessels)		04J71-060			
96 Deep Well Plates (32 Plates)		04J71-030			
96-Well Optical Reaction Plates (20 Plates)		04J71-070			
Optical Adhesive Covers (100 Covers)		04J71-075			
Master Mix Tubes/Caps (150 Tubes/Caps)		04J71-080			
Splash Free Support Base (5 each)		09K31-001			
13mm Sample Racks		04J72-082			
Optical Calibration Kit (1 each)		04J71-093			
Price per instrument				**Price per test result**	**$10.50 - 22.50***

* Please contact your local Abbott Molecular representative

Continued overleaf

Lab-based HIV EID, HIV VL, HCV VL – Abbott (RealTime) continued

HIV VIRAL LOAD

Instrument		**Reference number**	**FCA ($)**	**Cartridge/reagents**		**Reference number**
*m*24*sp* (not available in US)	Sample Extraction, up to 24 samples	03N06-001		*m*Sample Preparation Systems RNA (4x24 Preps)	Sample preparation, extraction reagent	04J70-024
*m*2000*sp*	Sample Extraction, up to 96 samples	09K14-002	$170,000	Abbott RealTi*m*e HIV-1 Amplification Reagent Kit CE (plasma and DBS)	1 kit (96 tests; 4 x 24 tests/pack)	02G31-010
*m*2000*rt*	Amplification and detection	09K15-001		Abbott RealTi*m*e HIV-1 Amplification Reagent Kit CE (plasma)	1 kit (96 tests; 4 x 24 tests/pack)	02G31-090
				Abbott RealTi*m*e HIV-1 Control Kit CE	1 kit (3 levels with 8 replicates per level)	02G31-080
				Abbott RealTi*m*e HIV-1 Calibrator Kit CE	1 kit (2 levels with 12 replicates per level)	02G31-070
				Abbott RealTi*m*e HIV-1 Amplification Including Uracil-N-Glycosylase (UNG) optional	1 tube, 112 µL, 1U/µL	02G31-066
				*m*Sample Preparation System DBS Buffer (for DBS) for use with 2G31-10	4 x 46 mL	09N02-01
				Abbott RealTi*m*e HIV-1 Amplification Reagent Kit FDA (plasma)	1 kit (96 tests; 4 x 24 tests/pack)	06L18-090
				Abbott RealTi*m*e HIV-1 Control Kit FDA	1 kit (3 levels with 8 replicates per level)	06L18-080
				Abbott RealTi*m*e HIV-1 Calibrator Kit FDA	1 kit (2 levels with 12 replicates per level)	06L18-070
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**FCA ($)**
RealTi*m*e HIV-1 Application CD-ROM CE	Application CD-ROM	01L68-14 or higher		None		
RealTi*m*e HIV-1 Application CD-ROM US FDA IVD	Startup kit for manual sample prep (cooler, 2 magnetic stands)	06L83				
Manual sample preparation startup kit*	Startup kit for manual sample prep (cooler, 2 magnetic stands)	02N28-01				
Disposable Tips (DiTis): 1mL (2304 Tips)		04J71-010				
Disposable Tips (DiTis): 200µL (2304 Tips)		04J71-017				
5mL Reaction Vessles (2000 Vessles)		04J71-020				
200 mL Reagent Vessles (90 Vessels)		04J71-060				
96 Deep Well Plates (32 Plates)		04J71-030				
96-Well Optical Reaction Plates (20 Plates)		04J71-070				
Optical Adhesive Covers (100 Covers)		04J71-075				
Master Mix Tubes/Caps (150 Tubes/Caps)		04J71-080				
Splash Free Support Base (5 each)		09K31-001				
13mm Sample Racks		04J72-082				
*m*2000system DBS PoSt Set (rack barcode)	needed for DBS usage	09N03-001				
Optical Calibration Kit (1 each)		04J71-093				
1.4 mL Internal Control Vial	needed for *m*24*sp*	03N19-001				
1.4 mL Internal Control Vial Cap	needed for *m*24*sp*	03N20-001				
Price per instrument			**$170,000****	**Price per test result**		**$10.50 - 22.50****

*Please note: DBS sample type does not include manual sample extraction

** Please contact your local Abbott Molecular representative

HCV VIRAL LOAD

Instrument		**Reference number**	**FCA ($)**	**Cartridge/reagents**		**Reference number**
*m*24*sp* (not available in US)	Sample Extraction, up to 24 samples	03N06-001		Abbott RealTi*m*e HCV Amplification Reagent Kit CE	1 kit (96 tests; 4 x 24 tests/ pack)	04J86-090
*m*2000*sp*	Sample Extraction, up to 96 samples	09K14-002	$170,000	Abbott RealTi*m*e HCV Control Kit CE	1 kit (3 levels with 8 replicates per level)	04J86-080
*m*2000*rt*	Amplification and detection	09K15-001		Abbott RealTi*m*e HCV Calibrator Kit CE	1 kit (2 levels with 12 replicates per level)	04J86-070
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**FCA ($)**
Abbott RealTi*m*e HCV Application CD-ROM	Application CD-ROM	01L69		None		
Manual sample preparation startup kit	Startup kit for manual sample prep (cooler, 2 magnetic stands)	02N28-01				
Disposable Tips (DiTis): 1mL (2304 Tips)	needed for *m*2000*sp* and *m*24*sp*	04J71-010				
Disposable Tips (DiTis): 200µL (2304 Tips)	needed for *m*2000*sp* and *m*24*sp*	04J71-017				
5mL Reaction Vessels (2000 Vessels)	needed for *m*2000*sp* and *m*24*sp*	04J71-020				
200 mL Reagent Vessels (90 Vessels)	needed for *m*2000*sp* and *m*24*sp*	04J71-060				
96 Deep Well Plates (32 Plates)	needed for *m*2000*sp* and *m*24*sp*	04J71-030				
96-Well Optical Reaction Plates (20 Plates)	needed for *m*2000*sp* and *m*24*sp*	04J71-070				
Optical Adhesive Covers (100 Covers)	needed for *m*2000*sp* and *m*24*sp*	04J71-075				
Master Mix Tubes/Caps (150 Tubes/Caps)	needed for *m*2000*sp* and *m*24*sp*	04J71-080				
Splash Free Support Base (5 each)	needed for *m*2000*sp* and *m*24*sp*	09K31-001				
13mm Sample Racks	needed for *m*2000*sp* and *m*24*sp*	04J72-082				
Optical Calibration Kit (1 each)	needed for *m*2000*sp* and *m*24*sp*	04J71-093				
1.4 mL Internal Control Vial	needed for *m*24*sp*	03N19-001				
1.4 mL Internal Control Vial Cap	needed for *m*24*sp*	03N20-001				
Price per instrument			**$170,000***	**Price per test result**		**$10.50 - 22.50***

* Please contact your local Abbott Molecular representative

HCV GENOTYPING

Instrument		**Reference number**	**FCA ($)**	**Cartridge/reagents**		**Reference number**
*m*24*sp* (not available in US)	Sample Extraction, up to 24 samples	03N06-001		Abbott RealTi*m*e HCV Genotype II Amplification Reagent Kit CE	24 tests	08K24-90
*m*2000*sp*	Sample Extraction, up to 96 samples	09K14-002	$170,000	Abbott RealTi*m*e HCV II Control Kit CE	4 positive, 4 negative	08K24-80
*m*2000*rt*	Amplification and detection	09K15-001				
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**FCA ($)**
Abbott RealTi*m*e HCV Genotype II *m*2000-System-Combined Application CD-rom	Application CD-ROM	08L36		None		
Disposable Tips (DiTis): 1mL (2304 Tips)		04J71-010				
Disposable Tips (DiTis): 200µL (2304 Tips)		04J71-017				
5mL Reaction Vessels (2000 Vessels)		04J71-020				
200 mL Reagent Vessels (90 Vessels)		04J71-060				
96 Deep Well Plates (32 Plates)		04J71-030				
96-Well Optical Reaction Plates (20 Plates)		04J71-070				
Optical Adhesive Covers (100 Covers)		04J71-075				
Master Mix Tubes/Caps (150 Tubes/Caps)		04J71-080				
Splash Free Support Base (5 each)		09K31-001				
13mm Sample Racks		04J72-082				
Optical Calibration Kit (1 each)		04J71-093				
1.4 mL Internal Control Vial	needed for *m*24*sp*	03N19-001				
1.4 mL Internal Control Vial Cap	needed for *m*24*sp*	03N20-001				
Price per instrument			**$170,000***	**Price per test result**		**Not provided**

* Please contact your local Abbott Molecular representative

Continued overleaf

Lab-based HIV EID, HIV VL, HCV VL – Abbott (RealTime) continued

03 | TIERED AND VOLUME-BASED PRICING | No Information Provided

04 | MAINTENANCE, WARRANTY & TRAINING

	Description
Leasing or reagent rental (RAP)	Abbott has options for reagent rental (RAP) agreements. The RAP agreements require certain terms and conditions to be met, including, but not limited to: contract term, volume, and amount of instrumentation. Specific criteria and considerations can vary and are negotiated on a case by case basis.
Installation	Provided : installation performed by Abbott service engineer or distributor service engineer certified by Abbott following internal SOP
Training	Provided: • Training done at customer site for up to 6 people. • Averages [*m*2000*sp*: training 3 days duration; *m*2000*rt*: 2 days; *m*2000*sp* and *m*2000*rt*: 4 days together] and is dependent on the number of assays. • After installation, training will be provided onsite (customer's site) for up to 6 technicians per session and in a maximum of 2 training sessions per laboratory. • The second training session can be done as a refresher (considered as on-going training) / Training materials and operator manual may be found on-line. • Done by Abbott Molecular or third party certified by Abbott as soon as the instrument installation is validated by the service engineer. • Languages: English, French, Spanish. • Done in real conditions / using true samples / using samples and material from the laboratory. • Content of training: - *m*2000 System Overview, Hardware Overview. - Good Laboratory Practices, Set-up RealTi*m*e extraction for all assays, RNA/DNA Extraction reagents. - Review of RealTi*m*e results. - Perform maintenance, decontamination procedure, troubleshooting, lamp replacement, optical calibration, and contamination check. • End user lab technician is certified by Abbott. Additional training on top of the 2 sessions will be on demand and charged.
Maintenance	• During the warranty period: repair is assured. • Following year 1 of the service contract, maintenance includes - Preventive maintenance - Repair visits - Phone support by molecular expert (Abbott Molecular engineer or third party engineer certified by Abbott) • Preventive maintenance = 1 PM/year - Software is upgraded as required - Phone support is available from 9am-5pm (depending on the country) • Repair maintenance is available 5 days/week from 9am-5pm - Spare parts are included - Can be purchased upfront or paid monthly/annually
Length(s) of warranty and additional costs for extended warranty / care plan	Warranty = 12 months
Warranty components	Installation, repair, spare parts, labour, initial training, phone support.
Turnkey option	Available on request.
In-country / regional technical support availability	Depends on country. Service assumed by Abbott Molecular service engineer or distributor service people certified by Abbott.

05 | CONTACT INFO

Dr. Anke Coblenz-Korte
Global Marketing Manager, Abbott Molecular

1350 E Touhy Ave
Des Plaines, IL 60018, USA

Website: abbottmolecular.com
Tel: +1-224-361-7971
Mobile: +1(630) 254-5674
Email: Anke.Coblenz-Korte@abbott.com

LAB-BASED HIV EID, HIV VL, HCV VL
BIOCENTRIC

01 | TECHNICAL AND PERFORMANCE INFORMATION

	HIV EARLY INFANT DIAGNOSIS	HIV VIRAL LOAD	HCV VIRAL LOAD
Company	**Biocentric**		
Product	**GENERIC HIV CHARGE VIRALE**	**GENERIC HIV CHARGE VIRALE**	**GENERIC HCV CHARGE VIRALE**
ASSAY			
Intended use (as per regulatory approval)	Qualitative or quantitative detection of HIV-1 DNA.	Quantitative determination of HIV-1 viral load in HIV infected patients (CE) Early Infant Diagnosis (RUO).	Quantitative determination of HCV viral load in HCV infected patients.
Principle of the assay	Real time PCR assay with fluorescence detection.	Real time RT-qPCR with fluorescence detection.	
Target	HIV-1 LTR (Long Terminal Repeat).		5'-UTR.
Genotypes and/or subtypes	HIV-1: Group M, B and non B subtypes, including CRF.		Genotypes 1 to 6.
Type of result	Qualitative and quantitative.	Quantitative	
Linear range	300 - 300,000 copies/mL = 6 - 6,000 copies DNA/PCR test.	Standard: 165 - 5,000,000 copies/mL Sensitive: 100-5,000,000 copies/mL	25-25,000,000 IU/mL
Output	Detection of HIV-1 DNA or quantitation of HIV-1 DNA copies/10^6 cells.	RNA viral load in copies/mL or IU/mL.	
DNA or RNA specific?	DNA	RNA	
Polyvalency	HIV-2 viral load, M. tuberculosis and drug resistance, HBV viral load.		
PERFORMANCE			
Sensitivity - analytical and clinical (source)	Input whole blood volume of 200µL: 40 copies/10^6 cells (= 6 DNA copies per PCR test).	Input plasma volume of 250µL: 416 copies/mL [CI 95%: 388 - 450 copies/mL] Input plasma volume of 1mL: 132 copies/mL [CI 95%: 119 - 149 copies/mL]	25-50 IU/mL
Specificity - analytical and clinical (source)	100%	100%	
Bias (source)	N/A	δ= 0,12 +/- 0.5 and 0.03 +/- 0.31 log copies/ml (from clinical comparative studies)	
Intra-assay precision (source)	Samples tested in duplicate (n = 172): Spearman, r = 0.940; p<0.0001	<4%	
Inter-assay precision (source)	<5%	<6%	
SAMPLE			
Sample preparation (steps)	Prepare DBS.	Prepare plasma.	
Sample type	Venous or capillary whole blood or PBMCs or DBS (RUO).	Plasma (EDTA or citrated) or DBS (RUO).	Plasma (EDTA or citrated).
Sample volume	Whole blood and PBMCs: 200µL DBS: 2 spots of ≈ 50µL WB each	Plasma: 250 or 1,000µL DBS: 2 spots of ≈ 50µL WB each	Plasma: 500µL DBS: 2 spots of 50 µl WB each
Sample stability	Whole blood: ≤6 hours at 15 - 30°C DBS: 1-2 weeks at 15 - 30°C; ≥2 weeks at 2 - 8°C	Plasma: ≤24 hours at 15 - 30°C; 5 days at 2 - 8°C; ≤1 year at -20°C DBS: 1-2 weeks at 15 - 30°C, ≥2 weeks at 2 - 8°C	Plasma: ≤24 hours at 15 - 30°C; 5 days at 2 - 8°C; ≤1 year at -20°C
Nucleic acid extraction method	Manual methods: - QIAamp DNA blood Mini kit (Qiagen REF 51106) - Nucleospin blood, Macherey (Nagel REF 740951-10 or 50 or 200) Automated (NorDiag Arrow system, DiaSorin Ireland) or GenoExtract (Hain Life Science, Germany)		
Time to result	4 hours	3.5 hours, including RNA isolation	
Capacity	180 - 360 patient samples per kit.		
Batching?	Yes		
Throughput per end-user per hour and/or 8hr day	One working day ≈ 40 samples	One working day: - one Arrow extractor = 40 samples - two Arrow extractors = 82 samples	

Continued overleaf

Product	GENERIC HIV DNA CELL	GENERIC HIV CHARGE VIRALE	GENERIC HCV CHARGE VIRALE
INSTRUMENT			
Size of device	40 x 45 x 46 cm		
Weight of device	30 kg		
Robustness	Not provided.		
Environmental requirements	Not provided.		
Power requirements	220 V		
Time to battery charge	N/A		
Battery duration (hours)	N/A		
Alternative charging options	External battery and UPS.		
Ease of use	Data station, printer option.		
Display languages	English and French.		
Built-in memory storage capacity	100 GB		
Connectivity options	Ethernet to LIMS.		
Interpretation of result	Qualitative or quantitative.	Viral load	
Instrument lifespan	10 years		
Other non-proprietary equipment required	For automated nucleic acid extraction.		
Regulatory approval	CE-Marked		
KIT			
Kit components	Primers, probes, enzyme mix, set of standards.	Primers, probes, enzyme mix, set of standards, internal control, positive and negative controls.	
Kit sizes	220 or 440 tests		
Internal control(s)	Yes		
Compatible with EQA and which?	CDC Proficiency Testing Programme.		TBD
Mean time between failures	Not provided.		
Transport and storage	Transport on dry ice ; storage at -20°C.		
Fridge at -80°C required?	No		
Shelf life (of each item in the kit)	12 months		
Performance protocol (steps)	(1) Preparation of sample and automatic extraction of nucleic acids. (2) Preparation of Master Mix and dispensing of nucleic acid eluates in PCR microplate, followed by PCR amplification. (3) Interpretation of results.		
Non-proprietary components required outside of the kit	None		
Regulatory approval	Generic HIV DNA Cell : RUO Generic HIV Charge Virale : CE-mark and WHO-PQ pending Generic HCV Charge Virale : RUO		
In-country approvals	Not provided.		
USAGE			
Technical skill required	Medium to highly trained in molecular biology; precision pipetting required.		
Applicable settings	Low- to medium-resourced settings.		
Laboratory set-up	1 Room with benches and electric plugs.		
Waste disposal requirements	Waste disposal for biological hazards.		

02 | PRICING

EARLY INFANT DIAGNOSIS							
Instrument		**Reference number**	**FCA Bandol (France)**	**Cartridge/reagents**		**Reference number**	**FCA ($)**
Fluorocycler	Realtime thermocycler 96 tests	7027002	$25,000	Generic HIV DNA Cell	220 tests	TR002-250	$1,540
	LED				440 tests	TR002-500	$2,900
	5 channels						
	with computer						
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
Arrow or GenoXtract (x2)	2 x 12-Sample automated extraction	8.31.01	$22,000*	GenoXtract Viral NA	96 tests	12.08.02	$620
	Ready-to-use cartridge			Arrow Viral NA Large Volume ref 6.11.02 USD 620			
	Disposable pumps						
	The package includes two instruments at US$11,000 each						
Cost per device			**$47,000**	**Cost per test result**			**$13.05**

HIV VIRAL LOAD							
Instrument		**Reference number**	**FCA ($)**	**Cartridge/reagents**		**Reference number**	**FCA ($)**
Fluorocycler	Realtime thermocycler 96 tests	7027002	$25,000	Generic HIV Charge Virale	220 tests	TR001-250IC TR001-440IC	$2,000
	LED				440 tests	TR001-440	$3,500
	5 channels						
	with computer						
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
Arrow or GenoXtract (x2)	2 x 12-Sample automated extraction	8.31.01	$22,000*	GenoXtract Viral Cartridge	96 tests	12.08.02	$620
	Ready-to-use cartridge			or Arrow Blood Viral NA			
	Disposable pumps			Proteinase K 1mL	100 mg/mL	405002100	$45
	The package includes two instruments at US$11,000 each						
Cost per device			**$47,000**	**Cost per test result**			**$14.9**

HCV VIRAL LOAD							
Instrument		**Reference number**	**FCA ($)**	**Cartridge/reagents**		**Reference number**	**FCA ($)**
Fluorocycler	Realtime thermocycler 96 tests	7027002	$25,000	Generic HCV Charge Virale	220 tests	TR005-250	$3,600
	LED				440 tests	TR005-440	$6,900
	5 channels						
	with computer						
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
Arrow or GenoXtract (x2)	2 x 12-Sample automated extraction	8.31.01	$22,000*	GenoXtract Viral Cartridge	96 tests	12.08.02	$620
	Ready-to-use cartridge			or Arrow Blood Viral NA			
	Disposable pumps			Proteinase K 1mL	100 mg/mL	405002100	$45
	The package includes two instruments at US$11,000 each						
Cost per device			**$47,000**	**Cost per test result**			**$22.60**

*For two instruments (i.e. $11,000 each).

Continued overleaf

Lab-based HIV EID, HIV VL, HCV VL – Biocentric continued

03 | TIERED AND VOLUME-BASED PRICING

No tiered or volume-based pricing provided.

04 | MAINTENANCE, WARRANTY & TRAINING

	Description	Cost ($)
Leasing or reagent rental (RAP)	Two 12-samples automated extraction instruments.	Approx. $1,300/month
Installation	Free of charge.	
Training	(1) Training takes 5 days (2) Available in English, French and German (3) On site training provided (4) Training material available as videos, manuals and slides (5) Possibility to adhere to ANRS proficiency program after training (6) Online training material available	Free of charge
Maintenance	Full on-site servicing (preventive and curative) as well as instrument swap, if necessary.	$5,500/year
Length(s) of warranty and additional costs for extended warranty / care plan	- 12 months warranty. - Extended warranty included in maintenance program.	Not provided.
Warranty components	On Thermocycler and Automated Extraction instrument.	Not provided.
Turnkey option	Includes: - 1 Realtime thermocycler - 3 automated extraction instruments - 1 microplate centrifuge - 2 mechanical pipette sets - 2 electronic pipettes - 1 PCR cabinet - 1 plate sealer	$65,000
In-country / regional technical support availability	Technical support centralized from France / Regional offices in South Africa and Kenya.	On request.

05 | CONTACT INFO

Marc Tordjeman
Biocentric, Director

276 Chemin des Roumpinas
Immeuble Horus, 83150 Bandol
France

Website: www.biocentric.com
Tel: +33 494 29 06 30
Mobile: +33 664 11 79 34
Email: biocentric@biocentric.com

LAB-BASED HIV VIRAL LOAD
BIOMÉRIEUX

01 | TECHNICAL AND PERFORMANCE INFORMATION

Company	BIOMÉRIEUX	Product	NUCLISENS EASYQ® HIV-1 V2.0
ASSAY		**PERFORMANCE**	
Intended use	Detection of isolated HIV-1 RNA. The test can be used to assess patient prognosis by measuring the baseline HIV-1 RNA level or to monitor the effects of antiretroviral therapy by measuring changes in plasma/DBS HIV-1 RNA levels during the course of antiretroviral treatment. Must not be used as a screening test for HIV-1 or as a diagnostic test to confirm the presence of HIV-1 infection.	**Sensitivity - analytical and clinical (source)**	Linear quantitative range: - Testing diluted samples from 9 to 79,000,000 copies/mL, derived from HIV-1 RNA reference material with two lots of NucliSENS EasyQ HIV-1 v2.0 reagents, demonstrated a direct proportional relationship between the dilution factor and the number of HIV-1 RNA copies reported. - The performance of the assay using EDTA plasma was found to give a linear response over a range of 25 to 79,000,000 copies/mL, for a 1 mL input of EDTA plasma, over a range of 50 to 15,000,000 copies/mL for a 0.5 mL input of EDTA plasma; over a range of 292 to 71,000,000 copies/mL for 0.1 mL input of EDTA plasma; and over a range of 500 to 21,000,000 copies/mL for DBS. (bioMérieux)
Principle of the assay	Real time NASBA isothermal signal amplification using molecular beacons for detection.		
Target	HIV-1 RNA gag	**Specificity - analytical and clinical (source)**	Observed specificity: N = 261 (1mL EDTA plasma) = 100% [95% CI (98.6 - 100)] N = 129 (0.1mL EDTA plama) = 100% [95% CI (97.2 - 100)] N = 100 DBS from randomly selected healthy blood donors = 100% [95% CI (96.4 - 100)] - All non-reactive for HIV-1 & HIV-2 antibodies (bioMérieux)
Genotypes and/ or subtypes	NucliSENS EasyQ® HIV-1 v2.0 demonstrated the capability to detect and quantify RNA from representative specimens of the major HIV-1 group M subtypes A to J. For DBS, NucliSENS EasyQ® HIV-1 v2.0 demonstrated the capability to detect and quantify RNA from the following subtypes: A, B, C, D, F, G, H and circulating recombinant form CRF02_AG. In addition to the above-described panels, various circulating recombinant forms and additional subtypes were tested in serial dilutions for EDTA plasma of the following NIBSC samples: ARP1050 (CRF01_AE), ARP1066 and ARP1037 (CRF02_AG, consisting of subtype A and G), ARP1038 (CRF11-cpx, consisting of subtype A, G, J and CRF01_ AE), ARP1034 (CRF14_BG, consisting of subtype and G) and ARP176 (GHAA, consisting of GH recombinant and A subtype), ARP1036 (subtype K) ARP1017.1 and ARP1017.2 (subtype J), ARP1043 (subtype H) and ARP190 (HIV-1 group N). All specimens were detected and the intended dilution factor used is well reflected by the results (data not shown).	**Bias (source)**	Not provided.
		Intra-assay precision (source)	Plasma: Viral quality assurance input: <79 copies/mL = 0.29 - 0.54 10Log 79 - 794 copies/mL = 0.19 - 0.28 10Log >794 copies/mL = 0.09- 0.10 10Log DBS: Viral quality assurance input: <710 copies/mL = 0,47 10Log 710 - 7100 copies/mL = 0.28 10Log >7100 copies/mL = 0.16 10Log (bioMérieux)
Type of result	Quantitative	**Inter-assay precision (source)**	The reproducibility was evaluated by testing the same reference sample at 3 different laboratory sites, and using 3 different reagent lots, giving a total of 123 results. The observed precision is 0.2210 log cps/ml (standard deviation), for a mean sample value of 4.710 log cps/ml (50000 cps/ml).
Linear range	25 - 10,000,000 copies/mL		
Output	Time-to-result: 2.5 - 3 hours		
DNA or RNA specific?	RNA	**Accuracy (source)**	Plasma: <0.25 10Log DBS: <0.30 10Log (bioMérieux)
Polyvalency	ARGENE® molecular menu: immunocomprised, meningitis, respiratory diseases RT-PCR kits. Contact bioMérieux for additional information.		

Continued overleaf

Lab-based HIV Viral Load – Biomérieux continued

Company	BIOMÉRIEUX	Product	NUCLISENS EASYQ HIV-1 V2.0
SAMPLE		**INSTRUMENT**	
Sample preparation (steps)	DBS collection and venipuncture whole blood collection: - Blood should be collected in sterile tubes by normal venipuncture techniques using EDTA as an anticoagulant and should be handled with the proper precautions. - After centrifugation (e.g. 10 minutes at 1,500 x g), the obtained plasma specimen should be used as sample input. - No special specimen preparation or fasting of the patient is necessary. - No adverse effects were observed using EDTA as the anticoagulant. - Any deviations from the described procedures should be validated by users in their own laboratory setting. DBS Collection: - Collect whole blood in a tube with EDTA-anticoagulant and, on the same day, spot 50 µL of blood on Whatman 903 Specimen Collection Paper (e.g. Proteinsaver 903 Card) using a calibrated device (e.g. pipette). - Note: Fill each printed circle with a SINGLE application of blood. Prevent spotting outside the circles. - Note: Avoid touching or smearing the blood spots. - Two spots are needed for the nucleic acid extraction procedure. - If blood spots cannot be prepared immediately after blood draw, the blood tubes should be stored in a refrigerator for up to 24 hours until spotting. - Dry the filter paper for at least 3 hours (and for a maximum of overnight) at room temperature (15 to 30 °C). Capillary whole blood collection: Collect the capillary blood using a lancet and a device without EDTA. Spot 50 µl of capillary blood on Whatman 903 Specimen Collection Paper (e.g. Proteinsaver 903 Card). Dry the filter paper for at least 3 hours (and at maximum overnight) at room temperature (15 to 30°C). Note: Fill each printed circle with a SINGLE application of blood. Prevent spotting outside the circles. Note: Avoid touching or smearing the DBS. Two spots are needed for the nucleic acid extraction procedure described below.	**Size of device**	MiniMAG: W 43.8 x D 11.4 x H 15.3 cm EasyMAG: W 100 x D 65 x H 53 cm EasyQ: W 42 x D 42 x H 22 cm
		Weight of device	MiniMAG: ±3.6 kg EasyMAG: ±125 kg EasyQ: ±20.5 kg
		Robustness	Yes, refer to mean-time between failures: EasyMAG = 384 days; EasyQ = 5 years.
		Environmental requirements	MiniMAG: - Temperature: 4 – 45°C Easy Mag: - Temperature: 15 - 30ºC - Relative humidity: ≤80%, non-condensing at 30ºC DB - Altitude: 0 - 2,500 meters above sea level EasyQ: - Temperature: 10 - 40ºC - Relative humidity: ≤90% - Tested according to IEC 68-2-1 test Ab (cold); IEC 68-2-2 test Bb (dry heat); and IEC 68-2-3 test Ca (damp heat)
		Power requirements	MiniMAG: 100-240 VAC, 47-63 Hz EasyMAG: 100-240 VAC, 50/60 Hz; power rating 400 W EasyQ: 100-120 VAC, 50/60 Hz, nominal (operating range 90-136 V) or 200-240 VAC, 50/60 Hz, nominal (operating range 180-256 V)
		Time to battery charge	N/A
		Battery duration (hours)	N/A
		Alternative charging options	N/A
		Ease of use	MiniMAG equipped with keypad. EasyMAG equipped with PC and touch screen. EasyQ equipped with PC and standard screen. Data from EasyQ HIV-1 stored on computer. Mini Strip Centrifuge (EasyQ) and printer (EasyMAG and EasyQ) available as additional options.
Sample type	EDTA plasma or dried blood spot (venous EDTA or capillary (without anticoagulant) whole blood spotted on card).		
Sample volume	Plasma: 0.1 / 0.5 / 1 mL DBS: 2 spots of 50µL each	**Display languages**	English, German, Italian, Spanish, French.
Sample stability	EDTA plasma specimens can be stored in NucliSENS Lysis Buffer for a maximum of: - 14 days at 2 - 8°C - 24 hours at ambient temperature (2 to 30°C) - 1 year at -70°C	**Built-in memory storage capacity**	Storage on the computer (capacity of 250 GB).
Nucleic acid extraction method	Semi-automated	**Connectivity options**	Can be linked with LIS using NucliSENtral, which is an integrated software on Windows XP that can be used to link NucliSENS easyMAG and NucliSENS EasyQ with a Laboratory Information System.
Time to result	Less than 3 hours, from sample to result (sample acquisition, extraction, amplification, detection).	**Interpretation of result**	Quantitative results in copies/mL. TND = Target not detected. Please refer to product package insert for detailed information of interpretation of results (section 8.2 of the package insert: "Reviewing results").
Capacity	Can be configurated to run 8 - 1,000 tests/day but only 8 - 140 tests/day if only one instrument is used.		
Batching?	Yes. Maximum run size: NucliSENS EasyMAG = 24 samples NucliSENS miniMAG = 12 samples NucliSENS EasyQ Analyser = 48 samples	**Instrument lifespan**	Approximately 8 years depending on usage conditions, usage frequency, and systems environment.
Throughput per end-user per hour and/or 8hr day	Around 140 samples can be tested per 8-hour shift if 1 EasyMAG and 1 EasyQ are used.	**Other non-proprietary equipment required**	Yes, please refer to Table 2: "Non-proprietary equipment and consumables".
		Regulatory approval	CE-IVD

Company	BIOMÉRIEUX	Product	NUCLISENS EASYQ HIV-1 V2.0
	KIT		**KIT**
Kit components	NucliSENS EasyQ HIV-1 v2.0 (48 tests) ref. 285033 contains: - 1 x CD-ROM - 6 x 6 mg calibrator - 6 x 1.5 mL calibrator diluent - 6 x 6 mg enzymes - 6 x 0.5 mL enzyme diluent - 6 x 15 mg primers - 6 x 1.4 mL primer diluent	**Performance protocol (steps)**	Please refer to product package insert sent in appendix, for detailed information on protocol and each step, depending on the sample which is used for testing.
		Non-proprietary components required outside of the kit	Yes, please refer to Table 2: "Non-proprietary equipment and consumables".
Kit sizes	48 tests	**Regulatory approval**	WHO PQ, CE-IVD (plasma and EDTA + capillary DBS)
Internal control(s)	Yes	**In-country approvals**	Please refer to bioMérieux for country-specific registration information.
Compatible with EQA and which?	HIV-1 RNA positive and negative controls are commercially available and can be obtained from several suppliers, e.g. Seracare/BBI, Acrometrix. For the positive control, bioMérieux recommends to use a viral concentration of approximately 5,000 copies/mL. Please refer to product package insert for detailed information.		**USAGE**
		Technical skill required	Medium-highly trained, precision pipetting required at low volumes.
Mean time between failures	EasyMAG: 384 days; EasyQ: 5 years	**Applicable settings**	Technology can be used at regional / central level or national reference (or comparable) laboratories. Access to decentralized settings via DBS.
Transport and storage	Amplification reagents: 2-8°C Extraction reagents (buffers 1, 2 and lysis buffer): 2-30°C Buffer 3 and magnetic silica: 2-8°C		
Fridge at -80°C required?	Not required unless EDTA plasma samples are stored for more than 1 month, in this case samples should be placed at -70°C and remain stable for a maximum of 1 year.	**Laboratory set-up**	Specialized; 2-3 dedicated areas required.
Shelf life	Minimum guaranteed shelf-lives at the time of packing are the following: >210 days: buffers 1, 2, 3; magnetic silica; lysis buffer; disposables >150 days: amplification reagents >120 days: extraction reagents	**Waste disposal requirements**	Containers for solid waste, container for liquid waste, waste plastic bags.

Continued overleaf

02 | PRICING

Prices are given as indication only and should be confirmed at quotation stage on a case by case basis.

Instrument		Reference number	EXW ($)
NucliSENS miniMAG	1-12 extractions/run	4700015	$20,000.00
NucliSENS EasyMAG	1-24 extractions/run	4700014	$80,000.00
Keyboard AZ		*280154*	
Keyboard QW		*280155*	
EasyMAG Biohit Adapter - US		*280147*	
EasyMAG Biohit Adapter - AU		*280148*	
EasyMAG Biohit Adapter - EU		*280149*	
EasyMAG Biohit Adapter - JP		*280150*	
EasyMAG Biohit Adapter - UK		*280151*	
NucliSENS EasyQ	48 samples/run	4700016	$45,000.00
Strip centrifuge	220V	285056	$1,500.00
UPS converters UPS APC 1,500 VA EU		413647	$1,450.00
Printer Lexmark E360DN 230V		93621	$400.00
bioMérieux DBS Puncher		411022	$2,500.00

Cartridge/reagents/consumables		Reference number	EXW ($)
NucliSENS lysis buffer 2mL	48 tests	200292	
NucliSENS Magnetic Extraction Reagents	48 tests	200293	
NucliSENS easyMAG extraction Buffer 1	4 x 1 litre	280130	
NucliSENS easyMAG extraction Buffer 2	4 x 1 litre	280131	
NucliSENS easyMAG extraction Buffer 3	4 x 1 litre	280132	
NucliSENS easyMAG magnetic silica	384 extractions	280133	
NucliSENS easyMAG extraction Lysis Buffer	4 x 1 litre	280134	
Disposables	48 x 8 tests	280135	
NucliSENS lysis buffer 2 ml	48 tests	200292	
NucliSENS Easy Q HIV-1 V2.0	48 tests	285033	

Instrument Accessories	Reference number	EXW ($)

Non-proprietary and proprietary equipment and consumables needed but not provided		Reference number	EXW ($)
For miniMAG			
Microtubes 1,5 ml	(500 tubes and 500 caps)	200294	
Centrifuge (1,500 x g) for Lysis buffer tube 15 mL			
Thermo shaker for 1.5 ml microtubes (Eppendorf)		5350000.013	
Highly recommended: vacuum pump with intermediate recipient for eluant (IBS Integra biosciences)		158320	
Vortex			
ELISA microplates			
Rack for 15 mL tubes			
Rack for 1.5 mL tubes			
Pipette 10 - 100 µL			
Pipette 20 - 200 µL			
Pipette 100 - 1,000 µL			
Non-filtered tips for vacuum			
Filtered tips 10 - 100 µL			
Filtered tips 20 - 200 µL			
Filtered tips 100 - 1,000 µL			
Detergent		1075552500	
For EasyMAG			
Filter tips for multichannel bioHIT	10 x 96 tips	280146	
EasyMAG disposables	48 x 8 tests	280135	
Strip Plates Greiner	100 x 96 wells	278303	
For EasyQ			
EasyQ 8-Tube Caps		285051	
EasyQ 8-Tube Strips		285048	
For DBS			
Whatman 903 Specimen Collection Paper, Whatman International Ltd (e.g Proteinsaver 903 Card)			
An envelope or plastic zip-lock bag			
Desiccant sachet (MiniPax Sorbent sachet 2grams, MultiSorb Technologies			
Humidity indicator			
Roller mixer		SRT6	

Cost per device				Cost per test result	±$23.40*

*EXW price not including cost of non-propietary equipment and consumables.

03 | TIERED AND VOLUME-BASED PRICING

No information provided.

04 | MAINTENANCE, WARRANTY & TRAINING

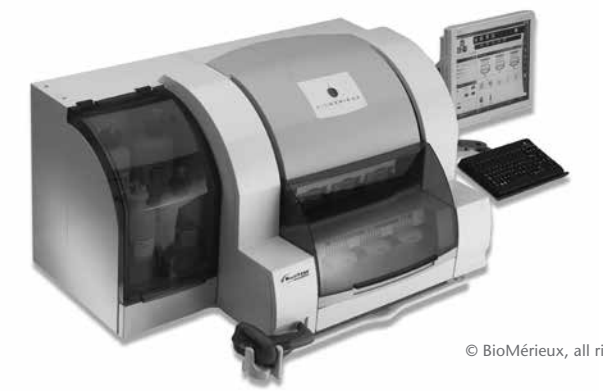
	Description
Leasing or reagent rental (RAP)	None provided.
Installation	Installation of the instrument, as per bioMérieux recommendations and procedures, consists of: - Unpacking the instrument - Bench positioning - Configuration of the instrument - Verification of the instrument - Validation of the functioning of the instrument
Training	Training of a maximum of 2 people in the laboratory during a maximum of 3 days. Travelling expenses are included. If more people are to be added to the training, an invoice will be issued based on a quotation. The people must have the required knowledge to use the instrument. Training on the system is on-site and consists of: - Principles of the technique - Use of the system - Interpretation of the results Manuals are available in: English, French, German, Italian, Spanish, Danish, Norwegian, Swedish, Portuguese, Russian, Romanian, Estonian and Czech. Software languages are available in: English, German, Italian, Spanish and French. Training materials consist of: - Worksheet materials explaining the steps to follow depending on the protocols used (simple front & quick user guide). These worksheets are available on the CD-ROM sent with the kit. - How-to-use video available for the use of DBS. Webinars can be organized on a case by case basis.
Maintenance	Maintenance performed during the warranty period as per bioMérieux recommendations and procedures consists of: - 2 preventive maintenances for Nuclisens EasyMag - 1 preventive maintenance for Nuclisens EasyQ - Corrective maintenance if failure occurs within the frame of our ongoing Export Sales General Conditions Preventive and corrective maintenance is provided by the bioMérieux legal representative in the country of destination following bioMérieux procedures and recommendations. Any warranty extension is studied on a case by case basis.
Length(s) of warranty and additional costs for extended warranty / care plan	A warranty period of 15 months is included in the price of the instrument, and is valid as of shipping date from the bioMérieux International Delivery Centre (Saint Vulbas, France). bioMérieux offers the possibility to extend the warranty. The conformance of the reagents to the specifications indicated in the package insert is guaranteed until their expiry date. Warranty services are provided by the bioMérieux legal representative in the country of destination following bioMérieux procedures and recommendations. Extended warranty includes: - 2 preventive maintenances for the Nuclisens EasyMag and 1 for the Nuclisens EasyQ - Corrective maintenance if failure occurs within the frame of our ongoing Export Sales General Conditions. Any warranty extension will be studied on a case by case basis and a quotation will be issued.
Warranty components	Included: - Instrument, parts and labour, within the frame of our ongoing Export Sales General Conditions. - Travelling expenses. Excluded: Disposables and replacement items with a normal life expectancy of less than 1 year (such as, but not limited to, batteries, lamps and tubing).
Turnkey option	Yes, to be discussed on a case by case basis.
In-country / regional technical support availability	bioMérieux has subsidiaries in 42 countries in the world and an extensive network of distributors to reach a presence in more than 160 countries worldwide. In Africa, the distribution and support relies on our network of distributors, supported by our subsidiary in South Africa and our offices in Ivory Coast, Egypt and Algeria. First level support is provided by bioMérieux local team and distributors. Second and third level support can be provided by our Global Customer Service, R&D, technical and supply teams.

05 | CONTACT INFO

Françoise Gay-Andrieu
Medical Affairs & Global Health

bioMérieux, Chemin de l'Orme
69280 Marcy L'Etoile, France

Website: www.biomerieux.com
Tel: +33 (0)4 78 87 20 00
Email: francoise.gay-andrieu@biomerieux.com



LAB-BASED HIV VIRAL LOAD
CAVIDI

01 | TECHNICAL AND PERFORMANCE INFORMATION

Company	**CAVIDI**		**Product**	**EXAVIR LOAD V3**	
ASSAY		**INSTRUMENT**		**KIT**	
Intended use (as per regulatory approval)	For determination of the activity of the enzyme reverse transcriptase (RT), as a marker of retroviral replication.	**Size of device**	Footprint on bench: <0.6 sqm	**Kit components**	Reagents + consumables
Principle of the assay	Determination of RT activity	**Weight of device**	12 kg	**Kit sizes**	32 samples / kit
Target	Reverse Transcriptase (RT)	**Robustness**	Very robust	**Internal control(s)**	HIV-I rRT Standard
Genotypes and/or subtypes	HIV-1 and HIV-2 and all subtypes	**Environmental requirements**	Laboratory	**Compatible with EQA and which?**	Yes, eg. NRL Australia and HUQAS Kenya
Type of result	Quantitative	**Power requirements**	AC power	**Mean time between failures**	No equipment failures recorded to date
Linear range	200 - 600,000 copies/mL				
Output	fg RT/mL and RNA copy equivalents/mL	**Time to battery charge**	N/A	**Transport and storage**	-14 to -25°C
DNA or RNA specific?	N/A				
Polyvalency	No	**Battery duration (hours)**	N/A	**Fridge at -80°C required?**	No
PERFORMANCE					
Sensitivity - analytical and clinical (source)	200 copies/mL	**Alternative charging options**	N/A	**Shelf life (of each item in the kit)**	2 years at customer
Specificity - analytical and clinical (source)	>99.5%	**Ease of use**	N/A	**Performance protocol (steps)**	Detailed in IfU, 21 steps over 2 days
Bias (source)	Not provided	**Display languages**	N/A	**Non-proprietary components required outside of the kit**	Pipette tips
Intra-assay precision (source)	4-8% CV				
Inter-assay precision (source)	2-3% CV	**Built-in memory storage capacity**	N/A	**Regulatory approval**	CE-IVD marked
SAMPLE					
Sample preparation (steps)	Prepare plasma from whole blood.			**In-country approvals**	Botswana, Zambia, Zimbabwe, Kenya, Uganda, Lesotho, India, Philippines and more.
Sample type	EDTA + Citrate plasma	**Connectivity options**	N/A		
Sample volume	1 mL			**USAGE**	
Sample stability	≤6 months at -20°C, >6 months at -80°C	**Interpretation of result**	N/A	**Technical skill required**	Lab Technician
Nucleic acid extraction method	N/A			**Applicable settings**	Near-POC / district hospital level
Time to result	48 hrs	**Instrument lifespan**	N/A	**Laboratory set-up**	Simple, not specialized, single work area, freezing required.
Capacity	32 samples per run	**Other non-proprietary equipment required**	ELISA plate reader, incubator, end-over-end mixing table, vortex, computer	**Waste disposal requirements**	Follow local SOPs for hazardous waste handling.
Batching?	Yes				
Throughput per end-user per hour and/or 8hr day	30-60 tests over 2 days	**Regulatory approval**	N/A		

02 | PRICING

Instrument		Reference number	EXW ($)	Cartridge/reagents		Reference number	EXW ($)
ExaVir Load Start-up equipment	230 V	59311	$4,500	ExaVir Load v3	Reagents & consumables to run 30 tests + 2 controls	55011	$360 - 750
ExaVir Load Start-up equipment	110 V	59310	$4,500				
Instrument Accessories		**Reference number**	**EXW ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**EXW ($)**
None				ELISA plate reader			
				Incubator			
				End-over-end mixing table			
				Vortex			
				Computer			
Cost per device			**$4,500**	**Cost per test result**			**$12-25**

03 | TIERED AND VOLUME-BASED PRICING

No information provided.

04 | MAINTENANCE, WARRANTY & TRAINING

	Description	Cost ($)
Leasing or reagent rental (RAP)	Purchase, leasing and reagent rental options can be offered.	Offered and negotiated upon request.
Installation	Wherever Cavidi has representation, installation is free of charge. If a new market, costs can be negotiated.	None
Training	• 4-5 days of training is needed • English and Portuguese available • On-site training available • Training tools are available as a training package/tools for before, under and after training. • End-users are considered proficient after training • Comprehensive training material is available for trainers and users.	Free of charge in countries where Cavidi has representation. If a new market, costs can be negotiated.
Maintenance (including instrument swap)	The ExaVir Load equipment only requires disinfection and wash. Maintenance of the microplate reader, while not part of our equipment supply, may be offered by the Cavidi local representative.	Cost varies depending on the make of reader and country and will be provided upon request.
Length(s) of warranty and additional costs for extended warranty / care plan	The ExaVir equipment is guaranteed (unlimited warranty) as long as the site is active.	None
Warranty components	Warranty covers all components of the ExaVir equipment.	N/A
Turnkey option	Can be offered upon request.	N/A
In-country / regional technical support availability	Yes	N/A

05 | CONTACT INFO

Fabio Baglioni
Cavidi, VP Global Sales & Marketing

Virdings Allé 2
SE-754 50 Uppsala, Sweden

Website: www.cavidi.com
Tel: +46 18 552040
Email: info@cavidi.se

LAB-BASED HIV VL & HCV VL
HOLOGIC

01 | TECHNICAL AND PERFORMANCE INFORMATION

	HIV VIRAL LOAD	HCV VIRAL LOAD
Company	**Hologic, Inc.**	
Product	**APTIMA HIV-1 QUANT DX ASSAY**	**APTIMA HCV QUANT DX ASSAY**
	ASSAY	
Intended use	Detection and quantitation of HIV-1 RNA. It is intended for use as an aid in the diagnosis of HIV-1 infection, including acute or primary infection, as a confirmation of HIV-1 infection, and as an aid in clinical management of patients infected with HIV-1. May be used as a supplemental test for specimens that have repeat reactive results with approved HIV immunoassays. If the specimen is reactive, HIV-1 infection is confirmed. May also be used in conjunction with clinical presentation and other laboratory markers for disease prognosis in HIV-1 infected individuals. When used as an aid in the diagnosis of HIV-1 infection, performance for qualitative results is established with both plasma and serum specimens. May be used as an aid in monitoring the effect of antiretroviral treatment by measuring changes in the concentration of HIV-1 RNA in plasma. When used as an aid in monitoring the effect of antiretroviral therapy, performance for quantitative results is established with plasma specimens only (serum Specimens may not be used for quantitative results). Not intended for use in screening blood or plasma donors.	Detection and quantitation of HCV RNA. Indicated for use as an aid in the diagnosis of active HCV infection in the following populations: - Individuals with antibody evidence of HCV infection with evidence of liver disease - individuals suspected of being actively infected with HCV following antibody evidence - individuals at risk of HCV infection with antibodies to HCV Detection of HCV RNA indicates that the virus is replicating and, therefore, is evidence of active infection. Indicated for use as an aid in the management of HCV infected patients undergoing HCV antiviral drug therapy. The assay measures HCV RNA levels at baseline, during treatment, and after treatment as well as determining sustained virological response (SVR). Assay performance characteristics will be established for individuals infected with HCV genotypes 1 through 6 treated with sofosbuvir-based regimens using drugs approved by the United States Food and Drug Administration (FDA), prescribed in accordance with FDA-approved labeling and/or the current American Association for the Study of Liver Diseases/Infectious Diseases Society of America (AASLD/IDSA) HCV treatment guidelines. No information is available on the assay's performance when other therapies are used. The results must be interpreted within the context of all relevant clinical and laboratory findings. Not intended for use as a screening test for the presence of HCV in blood or blood products.
Principle of the assay	Real-Time TMA	
Target	HIV-1 Pol and LTR	HCV 5' UTR
Genotypes and/ or subtypes	HIV-1 group M (A, B, C, D, F, G, H, CRF01_AE, CRF02_AG), group N, and group O	Genotypes 1-6
Type of result	Qualitative and quantitative	
Linear range	30-10e6 copies/mL	10-100 million IU/mL
Output	Qualitative output: Reactive or Non-reactive Quantitative output: viral load in copies/mL	Qualitative output: Reactive or Non-reactive Quantitative output: viral load in IU/mL
DNA or RNA specific?	RNA	
Polyvalency	Available: Chlamydia diagnosis, Gonorrhoea diagnosis, Chlamydia/Gonorrhoea combined diagnosis, Trichomonas vaginalis diagnosis, and HPV diagnosis and genotyping. In development: HBV viral load, Mycoplasma genitalium, HSV 1/2, Bacterial Vaginosis, Candida, Influenza A, B, RSV, Parainfluenza 1,2,3,4, Adenovirus, Human Metapneumovirus, and Rhinovirus.	
	PERFORMANCE	
Sensitivity - analytical and clinical (source)	13.1 copies/mL (95% detected in 500mL plasma) Source: Package insert	4.3 IU/mL (for plasma) and/or 3.9 IU/mL (for serum). Source: Package insert
Specificity - analytical and clinical (source)	100% (CI 99.4 - 100%). Results on 120 fresh and 510 frozen plasma and serum samples. Source: Package Insert	100% (736 samples, 95% CI: 99.6-100%). Specificity tested in fresh and frozen plasma and serum samples. Source: Package insert
Bias (source)	Bias is 0.30 log copies/mL for target concentration 1.24 log copies/mL. Source: Package insert	Bias is -0.33 log IU/mL for target concentration 1 log IU/mL. Source: Package insert
Intra-assay precision (source)	At 2.95 log copies/mL, the SD was 0.09 and CV(%) was 3.04. Source: Package insert	At 3.02 log IU/mL, the SD was 0.09 and CV(%) was 3.08. Source: Package insert
Inter-assay precision (source)	At 2.95 log copies/mL, the SD was 0.10 and CV(%) was 3.20. Source: Package insert	At 3.02 log IU/mL, the SD was 0.01 and CV(%) was 0.33. Source: Package insert

Product	APTIMA HIV-1 QUANT DX ASSAY	APTIMA HCV QUANT DX ASSAY
SAMPLE		
Sample preparation	Plasma and serum: after centrifugation, uncap primary blood tube and load onto system.	
Sample type	Plasma and serum. Hologic has developed a protocol for DBS that will be used to evaluate performance of the assay with this sample type. Hologic is investigating whether it will pursue regulatory certification for DBS.	
Sample volume	≥1.2mL in primary tubes, 700mL in specimen aliquot tubes, and 240mL with a 1:3 dilution in specimen aliquot tubes.	
Sample stability	Whole blood is stable for 24hrs at 2-30°C prior to centrifugation. Plasma is stable for 3 days in the primary tube or 5 days in secondary tubes at 2-8°C or 90 days in secondary tubes at -20°C or -70°C. Serum is stable for 5 days in primary or secondary tubes at 2-8°C or 7 days or in secondary tubes at -20°C.	Target: Whole blood is stable for 6hrs at 2-30°C prior to centrifugation. Plasma is stable for 24hrs in primary or secondary tubes at 2-25°C; 5 days in primary or secondary tubes at 2-8°C; or 60 days in secondary tubes at -20°C. Serum is stable for 24hrs in primary or secondary tubes at 2-30°C; 5 days in primary or secondary tubes at 2-8°C; or 60 days in secondary tubes at -20°C. Note: Performance characteristics have not yet been established.
Nucleic acid extraction method	Automated (platform is completely automated from sample to result).	
Time to result	Time to first 5 results is 2hr and 41 minutes, with additional 5 results every 5 minutes.	
Capacity	The Panther holds 8 sample racks of 15 samples per rack, thus on-board capacity is 120 specimens. Additional samples can be loaded every 15 minutes.	
Batching?	The Panther is NOT a batch system - users can continuously load samples at any time (random access). Controls are only needed every 24 hours or every 100 test kit.	
Throughput per end-user per hour and/or 8hr day	2 hours and 41 minutes to deliver the first 5 results, with an additional 5 results every 5 minutes. 324 samples/8 hours. At max capacity: 60 results/hr.	
INSTRUMENT		
Size of device	W x D x H: 122.0 x 81.5 x 175.0 cm. UPS (W x D x H): 21.4 x 41.0 x 32.5 cm.	
Weight of device	345kg. UPS (optional): 34.5kg.	
Robustness	• Direct tube sampling capability of primary tube and no processing of sample prior to loading onto the instrument. • Random Access Capability using on board sample barcode readers with samples and assay requests performed in a random manner, allowing samples to be loaded and tested as they are received throughout the day. • A reagent identification system (barcode or other) to automatically link reagent lot and expiration date information to the sample report. • Positive Sample Identification with ability to load samples and let the system run by itself automatically. • Reagent dispense verification and liquid level sensing capability to verify proper dispense of sample and reagents into reaction tube. • The ability to automatically decontaminate and remove amplification reaction tubes from the assay processing area without operator intervention in a closed system. • Ability to perform maintenance steps automatically at times scheduled by operator.	
Environmental requirements	Environment: indoor use only. Can be placed in general purpose lab and independent molecular lab not required Sunlight: No direct sunlight - sunlight may mislead optical sensors and affect performance Dust: No excessive dust Altitude: ≤2,000m above sea level Temperature: Ambient Operating 15–30°C; Storage 5–45°C; Transport -20–70°C Relative Humidity: Operating 20-85% non-condensing; Storage 10-90% non-condensing; Transport 10-90% non-condensing Pollution Degree: 2 Installation Class: 2	
Power requirements	Voltage: 100-240 + 10% VAC Frequency: 50-60Hz, single phase Current Input: Minimum of 15 amp circuit (dedicated); 20 amp circuit (dedicated if used with optional UPS) Current Draw: Average 700W; Peak 1400W; 100 VAC circuit draws 13 amps, 240 VAC circuit draws 5.4 amps Fuse: Thermal circuit breaker	
Time to battery charge	N/A	
Battery duration	N/A	
Alternative charging options	N/A	
Ease of use	The Panther has a touchscreen monitor connected to the system and a printer is included.	
Display languages	English	
Built-in memory storage capacity	250 GB	
Connectivity options	The Panther hosts bi-directional LIS connectivity.	

Continued overleaf

Lab-based HIV VL & HCV VL – Hologic continued

Product	APTIMA HIV-1 QUANT DX ASSAY	APTIMA HCV QUANT DX ASSAY
INSTRUMENT		
Interpretation of result	Reported Aptima HIV-1 Quant Dx Results / Quantitative Interpretation / Qualitative Intepretation. Not Detected / HIV-1 RNA not detected / Non-reactive for HIV-1 RNA. <30 detected / HIV-1 RNA is detected but at a level below the Lower Limit of Quantitation (LLOQ) / Reactive for HIV-1 RNA. 30 - 10,000,000 / HIV-1 RNA concentration is within the linear range of 30 - 10,000,000 copies/mL / Reactive for HIV-1 RNA. >10,000,000 / HIV-1 RNA concentration is above the Upper Limit of Quantitation (ULOQ) / Reactive for HIV-1 RNA.	Reported Aptima HCV Quant Dx Results Quantitative Interpretation / Qualitative Intepretation[1]. Not Detected / HCV RNA not detected / Non-reactive for HCV RNA. <10 detected / HCV RNA is detected but at a level below the Lower Limit of Quantitation (LLOQ) / Reactive for HCV RNA. 10 - 100,000,000 / HCV RNA concentration is within the linear range of 10 - 100,000,000 IU/mL / Reactive for HCV RNA. >100,000,000 / HCV RNA concentration is above the Upper Limit of Quantitation (ULOQ) / Reactive for HCV RNA. Invalid2: there was an error in the generation of the result. Specimen should be retested. 1. A diagnostic interpretation may be made from either serum or plasma specimens that have not been diluted. 2. Invalid results are displayed in blue coloured font.
Instrument lifespan	7-10 years	
Other non-proprietary equipment required	No other third party equipment is required.	
Regulatory approval	N/A	
KIT		
Kit components	Assay Kit: Assay Box: TCR (liquid format), Enzyme, Amplification, and Promoter reagents (lyophilized with individual reconstitution solutions) Control Kit: Negative, Low Positive, and High Positive Calibrator Kit: Calibrator tube	
Kit sizes	100 tests	
Internal control(s)	Internal control is formulated into the TCR and run in every sample.	
Compatible with EQA and which?	Acrometrix, QCMD, WHO standard	
Mean time between failures	Average = 1,200 hours globally. This reflects new vs experienced uses as well as high vs. low volume labs. By company definition, this includes instrument repairs as well as user inquiries not requiring a repair.	
Transport and storage	Assay Box: stored at 2-8°C, shipped at controlled ambient temperature. Calibrator and Control Box: stored and shipped at -15°C to -35°C.	
Fridge at -80°C required?	No	
Shelf life (of each item in the kit)	Maximum shelf life = 24 months post manufacturing.	Current maximum shelf life is 24 months for the CE-IVD product (PRD-03506)
Performance protocol	1. Centrifuge blood tube to separate plasma or serum 2. Prepare reagents, load onto The Panther rack, and load on The Panther 3. Load samples onto The Panther rack, uncap tubes, and load on The Panther 4. If samples do not have barcodes, manually enter sample ID into system 5. Close The Panther door and The Panther will start assay processing and report results when complete	
Non-proprietary components required outside of the kit	All consumables, both proprietary and non-proprietary, and assay fluids needed to perform testing on The Panther system are included and automatically calculated when ordering the Aptima Assay. The list of consumables that are included is provided below: - Multi-tube units (MTUs) – reaction vessel used on The Panther - Waste Bags for The Panther - The Panther Waste Bin Cover - Assay Fluids needed to run The Panther - Tecan tips used on The Panther These are provided free of charge and how many of each that will be needed per instrument is calculated based on the number of tests ordered.	
Regulatory approval	Aptima HIV-1 Quant Dx assay was CE/IVD certified Nov 2014. The FDA approval of this assay obtained in Dec 2016. The assay was submitted for WHO Prequalificaiton.	CE-IVD (Nov 2015) and FDA (Feb 2017) approvals.
In-country approvals	Product is approved in US, CE, Australia and Canada. Pending submission for China, Japan and Thailand	
USAGE		
Technical skill required	Minimal skill level, no pipetting needed.	
Applicable settings	Can be run in general laboratory with minimal infrastructure requirements.	
Laboratory set-up	General purpose laboratory.	
Waste disposal requirements	Bleach automatically added by The Panther system to each specimen after run. Waste disposal handled according to country regulations.	

02 | PRICING

HIV VIRAL LOAD							
Instrument		**Reference number**	**FCA ($)**	**Cartridge/reagents**		**Reference number**	**FCA ($)**
The Panther System	1 integrated automated platform with on-board computer. Printer included.	PRD-303095	$150,000 - 175,000	Aptima HIV-1 Quant Dx Assay Kit	Assay kit 100 tests (includes 1 assay box, 1 Calibrator kit, and 1 Control kit). Multi-tube units (MTUs), The Panther Waste Bag Kit, The Panther Waste Bin Cover, Aptima Assay Fluids, and Tips are included (and calculated based on number of kits ordered).	PRD-03000	$10-$25
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
None				None			
Price per instrument			**$150,000 - 175,000**	**Price per test result**			**$10-$25**

HCV VIRAL LOAD							
Instrument		**Reference number**	**FCA ($)**	**Cartridge/reagents**		**Reference number**	**FCA ($)**
The Panther System	1 integrated automated platform with on-board computer. Printer included.	PRD-303095	$150,000 - 175,000	Aptima HCV Quant Dx Assay Kit	Assay kit 100 tests (includes 1 assay box, 1 Calibrator kit, and 1 Control kit). Multi-tube units (MTUs), The Panther Waste Bag Kit, The Panther Waste Bin Cover, Aptima Assay Fluids, and Tips are included (and calculated based on number of kits ordered).	PRD-03506	$10-$25
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
None				None			
Price per instrument			**$150,000 - 175,000**	**Price per test result**			**$10-$25**

03 | TIERED AND VOLUME-BASED PRICING

No information provided.

Continued overleaf

Lab-based HIV VL & HCV VL – Hologic continued

04 | MAINTENANCE, WARRANTY & TRAINING

	Description
Leasing or reagent rental (RAP)	Instrument purchase or reagent rental are available based on contractual volume commitments.
Installation	Included in instrument purchase or reagent rental, estimated at less than 3 days.
Training	Training for 2 individuals is included in instrument purchase or reagent rental, estimated at 5 days, and includes proficiency prior to the start of clinical testing.
Maintenance	Year 1: full warranty Year 2 and beyond: service contract available for purchased instruments or included in reagent rental
Length(s) of warranty and additional costs for extended warranty / care plan	12 month warranty included in instrument purchase. Annual service contract offered after warranty period. Instrument service and support included in reagent rental.
Warranty components	Warranty includes: - labour - travel expenses - replacement parts - preventative maintenance - access to technical support - factory authorized updates or modifications - up to two Pro360 and/or LIS configuration changes
Turnkey option	N/A
in-country / regional technical support availability	In-country/regional service and support will be offered locally by contractors or distributors.

05 | CONTACT INFO

Dejan Drljaca
Global Business Strategic Leader /
Emerging Markets Hologic

10210 Genetic Center Drive
San Diego, CA 92121 USA

Website: www.hologic.com
www.aptimavirology.com
Tel: (858) 410-7908
Email: dejan.drljaca@hologic.com

LAB-BASED HIV VL, HCV VL
QIAGEN

01 | TECHNICAL AND PERFORMANCE INFORMATION

	HIV VIRAL LOAD		HCV VIRAL LOAD	
Company	**Qiagen**			
Product	**ARTUS HI VIRUS-1 RG RT-PCR**	**ARTUS HI VIRUS-1 QS-RGQ**	**ARTUS HCV RG RT-PCR**	**ARTUS HCV QS-RGQ**
ASSAY				
Intended use	Quantitation of HIV-1 RNA. Intended for use in conjunction with clinical presentation and other laboratory markers for disease prognosis and for use as an aid in assessing viral response to antiretroviral treatment, as measured by changes in EDTA plasma HIV-1 RNA levels. Not intended to be used as a screening test for HIV or as a diagnostic test to confirm the presence of HIV infection.		Quantitation of HCV RNA. Intended for use in conjunction with clinical presentation and other laboratory markers for disease prognosis and for use as an aid in assessing viral response to antiviral treatment as measured by changes in EDTA plasma HCV RNA levels. Not intended to be used as a screening test for HCV or as a diagnostic test to confirm the presence of HCV infection.	
Principle of the assay	Real time PCR			
Target	HIV-1 RNA LTR		HCV RNA, 240 nt region of the 5' UTR	
Genotypes and/ or subtypes	HIV-1: Group M (A-H)		HCV genotypes 1–6	
Type of result	Quantitative			
Linear range	60 - 50,000,000 copies/mL	45 - 45,000,000 (LOD 34 copies/mL)	65 - 1,000,000 IU/mL	35 - 17,700,000 IU/mL
Output	Viral load			
DNA or RNA specific?	No			
Polyvalency	HBV, CMV, EBV, BKV, VZV, HSV, CT, M. tuberculosis	HBV, CMV, EBV, BKV, VZV, HSV, C.Diff., VanR, CT/NG, GBS.	HBV, CMV, EBV, BKV, VZV, HSV, CT, M. tuberculosis	HBV, CMV, EBV, BKV, VZV, HSV, C.Diff., VanR, CT/NG, GBS.
PERFORMANCE				
Sensitivity - analytical and clinical (source)	4.5 IU/µL (analytical)	34.4 copies/mL (analytical)	33.6 IU/mL (analytical)	21.6 IU/mL (analytical)
Specificity - analytical and clinical (source)	Not provided			
Bias (source)	Not provided			
Intra-assay precision (source)	Not provided			
Inter-assay precision (source)	Not provided			
SAMPLE				
Sample preparation (steps)	Not provided			
Sample type	Plasma			
Sample volume	500µL	1,000µL	500µL	1,000µL
Sample stability	Not provided			
Nucleic acid extraction method	Manual (QIAamp DSP Virus Kit)	Automated	Manual (QIAamp DSP Virus Kit)	Automated
Time to result	5–6 hours			
Capacity	≤96 samples			
Batching?	Yes, flexible batch size.			
Throughput per end-user per hour and/or 8hr day	≤67 samples/run			

Continued overleaf

Lab-based HIV VL, HCV VL – Qiagen continued

Product	ARTUS HI VIRUS-1 RG RT-PCR	ARTUS HI VIRUS-1 QS-RGQ	ARTUS HCV RG RT-PCR	ARTUS HCV QS-RGQ
INSTRUMENT				
Size of device	W 37 x H 28.6 x D (without cables) 42 / D (door open) 53.8cm	QIAsymphony SP/AS – QIAsymphony SP: 128 x 103 x 73cm QIAsymphony AS: 59 x 103 x 73cm QIAsymphony SP/AS (integrated operation): 185 x 103 x 73cm Rotor-Gene Q: W 37 x H 28.6 x D (without cables) 42 / D (door open) 53.8cm	W 37 x H 28.6 x D (without cables) 42 / D (door open) 53.8cm	QIAsymphony SP/AS – QIAsymphony SP: 128 x 103 x 73cm QIAsymphony AS: 59 x 103 x 73cm QIAsymphony SP/AS (integrated operation): 185 x 103 x 73cm Rotor-Gene Q: W 37 x H 28.6 x D (without cables) 42 / D (door open) 53.8cm
Weight of device	12.5kg, standard configuration	QIAsymphony SP: 175kg QIAsymphony AS: 90kg QIAsymphony SP/AS (integrated operation): 265kg Rotor-Gene Q: 12.5kg (standard configuration)	12.5kg, standard configuration	QIAsymphony SP: 175kg QIAsymphony AS: 90kg QIAsymphony SP/AS (integrated operation): 265kg Rotor-Gene Q: 12.5kg (standard configuration)
Robustness	Not provided			
Environmental requirements	For indoor use only			
Power requirements	100–240 V AC, 50–60 Hz, <520 VA (peak) Power consumption <60 VA (standby) Mains supply voltage fluctuations are not to exceed 10% of the nominal supply voltages F5a 250 V fuse	QIAsymphony SP/AS: 100–240 V AC, 50–60 Hz, 1,400 VA, mains supply voltage are not to exceed 10% of nominal supply voltages Rotor-Gene Q: 100–240 V AC, 50–60 Hz, 520 VA (peak) Power consumption 8 VA (standby) Mains supply voltage fluctuations are not to exceed 10% of the nominal supply voltages F5A 250 V fuse	100–240 V AC, 50–60 Hz, <520 VA (peak) Power consumption <60 VA (standby) Mains supply voltage fluctuations are not to exceed 10% of the nominal supply voltages F5a 250 V fuse	QIAsymphony SP/AS: 100–240 V AC, 50–60 Hz, 1,400 VA, mains supply voltage are not to exceed 10% of nominal supply voltages Rotor-Gene Q: 100–240 V AC, 50–60 Hz, 520 VA (peak) Power consumption 8 VA (standby) Mains supply voltage fluctuations are not to exceed 10% of the nominal supply voltages F5A 250 V fuse
Time to battery charge	N/A			
Battery duration (hours)	N/A			
Alternative charging options	None			
Ease of use	None	Touch screen	None	Touch screen
Display languages	English			
Built-in memory storage capacity	None			
Connectivity options	Q!Alink software (for automated data transfer between QIAsymphony RGQ and LIMS).			
Interpretation of result	None			
Instrument lifespan	Not provided			
Other non-proprietary equipment required	Vortex mixer, Benchtop centrifuge			
Regulatory approval	CE-IVD	CE-IVD	CE-IVD	CE-IVD

Product	ARTUS HI VIRUS-1 RG RT-PCR	ARTUS HI VIRUS-1 QS-RGQ	ARTUS HCV RG RT-PCR	ARTUS HCV QS-RGQ
KIT				
Kit components	2 Masters, 4 Quantitation Standards, Internal Control, Water (PCR grade)			
Kit sizes	24 or 96 reactions	24 or 72 reactions	24 or 96 reactions	24 or 72 reactions
Internal control(s)	Yes			
Compatible with EQA and which?	Yes, QCMD			
Mean time between failures	Not provided			
Transport and storage	Store the kit at -20°C, with some variation by reagent, transport on dry ice.			
Fridge at -80°C required?	No			
Shelf life (of each item in the kit)	All reagents are stable until the expiration date stated on the label			
Performance protocol (steps)	Not provided			
Non-proprietary components required outside of the kit	None			
Regulatory approval	CE-IVD	CE-IVD	CE-IVD	CE-IVD
In-country approvals	Not provided			
USAGE				
Technical skill required	Medium to highly trained, precision pipetting required at low volumes.			
Applicable settings	Mid- to highly-resourced settings	Highly-resourced settings	Mid- to highly-resourced settings	Highly-resourced settings
Laboratory set-up	3 dedicated areas are required	2 dedicated areas are required	3 dedicated areas are required	2 dedicated areas are required
Waste disposal requirements	Not provided			

02 | PRICING

HIV & HCV VIRAL LOAD

Instrument		Reference number	FCA ($)	Cartridge/reagents		Reference number	FCA ($)
QIAsymphony RGQ	QIAsymphony SP, QIAsymphony AS, Rotor-Gene Q 5plex HRM; includes required accessories and consumables, installation, and training; includes 1-year warranty on parts and labour	9001850	Enquire	QIAamp DSP Virus Kit	For 50 preps: QIAamp MinElute Columns, buffers, reagents, tubes, column extenders, VacConnectors. For use with the artus RG kit variants	60704 4513363 artus HI Virus-1 QS-RGQ Kit (24) CE 4513366 artus HI Virus-1 QS-RGQ Kit (72) CE 4518363 artus HCV QS-RGQ Kit (24) CE 4518366 artus HCV QS-RGQ Kit (72) CE	
Rotor-Gene Q 5plex HRM system	Real-time PCR cycler and High Resolution Melt Analyser with 5 channels (green, yellow, orange, red, crimson) plus HRM channel, laptop computer, software, accessories: includes 1-year warranty on parts and labour, installation and training	9001650	Enquire	QIAsymphony DSP Virus/ Pathogen Midi Kit	For 96 preps (1,000µL each): includes 2 reagent cartridges and enzyme racks and accessories; for use with the QIAsymphony RGQ system	937055 4513263 artus HI Virus-1 RG RT-PCR Kit (24) CE 4513265 artus HI Virus-1 RG RT-PCR Kit (96) CE 4518263 artus HCV RG RT-PCR Kit (24) CE 4518265 artus HCV RG RT-PCR Kit (96) CE	

Instrument Accessories	Reference number	FCA ($)	Non-proprietary equipment and consumables	Reference number	FCA ($)
None			Vortex mixer		
			Benchtop centrifuge		
Cost per device		**Not provided**	**Cost per test result**		**$16 - 45**

Continued overleaf

Lab-based HIV VL, HCV VL – Qiagen continued

03 | TIERED AND VOLUME-BASED PRICING

No information provided.

04 | MAINTENANCE, WARRANTY & TRAINING

	QSRGQ		ROTORGENE Q	
	Description	**Cost ($)**	**Description**	**Cost ($)**
Leasing or reagent rental (RAP)	Possible	N/A	Possible	N/A
Installation	• Installation of the system hardware and software • Introductory training • Help customer to get started quickly	$7,000 - 9,000	• Installation of the system hardware and software • Introductory training • Help customer to get started quickly	$2,000 - 3,000
Training	• 2-5 days required • English + local languages, if available • On site training possible • Training tools available • Certified user after training completed	~$1,500 - 3,000 per day	• 1-2 days required • English + local languages, if available • On site training possible • Training tools available • Certified user after training completed	~$1,500 - 3,000 per day
Maintenance (including instrument swap)	• Inspection of all components of the equipment • Bring the instrument to its optimal performance • Ensure instrument is performing according to specification	$5,000 - 7,000	• Inspection of all components of the equipment • Bring the instrument to its optimal performance • Ensure instrument is performing according to specification	$1,500 - 1,900
Length(s) of warranty and additional costs for extended warranty / care plan	1 year manufacturer warranty on parts, labour, and travel	10% instrument LP for extended warranty, 48hr response time, 1 on-site preventative maintenance	1 year manufacturer warranty on parts, labour, and shipping	10% instrument LP for extended warranty, 48hr response time via loaner instrument, 1 on-site inspection service
Warranty components	Parts, labour, travel	N/A	Parts, labour, shipping	N/A
Turnkey option	N/A			
In-country / regional technical support availability	Yes	N/A	Yes	N/A

05 | CONTACT INFO

Carsten Lange
Senior Global Product Manager, Infectious Diseases

QIAGEN GmbH, Qiagen Strasse 1
40724 Hilden, Germany

Website: www.qiagen.com
Email: Carsten.Lange@qiagen.com

01 | TECHNICAL AND PERFORMANCE INFORMATION

	HIV EID	HIV VIRAL LOAD		
Company	**Roche Molecular Diagnostics**			
Product	**COBAS®AMPLIPREP/ COBAS® TAQMAN® HIV-1 QUALITATIVE TEST, VERSION 2.0**	**COBAS®AMPLIPREP/ COBAS® TAQMAN® HIV-1 TEST, VERSION 2.0**	**COBAS® HIV-1 FOR USE ON THE COBAS® 4800 SYSTEM**	**COBAS® HIV-1 FOR USE ON THE COBAS® 6800/8800 SYSTEMS**
	ASSAY			
Intended use	In vitro diagnostic, total nucleic acid amplification test for the qualitative detection of HIV-1 DNA and RNA (or total nucleic acid, TNA.) The test is a diagnostic test, indicated for individuals who are suspected to be actively infected with HIV-1. Detection of HIV-1 TNA is indicative of active HIV infection. Infants born to mothers infected with HIV-1 may have maternal antibodies to HIV-1, and the presence of HIV-1 nucleic acid in the infant indicates active HIV-1 infection. In adults, the test may be used as an aid in the diagnosis of HIV-1 infection.	In vitro nucleic acid amplification test for the quantitation of HIV-1 RNA. This test is intended for use in conjunction with clinical presentation and other laboratory markers ofdisease progress for the clinical management of HIV-1 group M and HIV-1 group O infected patients. The test can be used to assess patient prognosis by measuring the baseline HIV-1 RNA level or to monitor the effects of antiretroviral therapy by measuring changes in HIV-1 RNA levels during the course of antiretroviral treatment.	In vitro nucleic acid amplification test for the quantitation of HIV-1 RNA. This test is intended for use in conjunction with clinical presentation and other laboratory markers of disease progression for the clinical management of HIV-1-infected patients. This test can be used for confirmation of HIV-1 infection in antibody reactive individuals, and to assess patient prognosis by measuring the baseline HIV-1 level, or to monitor the effects of antiretroviral therapy by measuring changes in HIV-1 RNA levels during the course of antiretroviral treatment.	US-IVD: In vitro nucleic acid amplification test for the quantitation of HIV-1 RNA. This test is intended for use in conjunction with clinical presentation and other laboratory markers for the clinical management of HIV-1 infected patients. The test can be used to assess patient prognosis by measuring the baseline HIV-1 level or to monitor the effects of antiretroviral therapy by measuring changes in HIV-1 RNA levels during the course of antiretroviral treatment. cobas® HIV-1 is not intended for use as a screening test for the presence of HIV-1 in donated blood or plasma or as a diagnostic test to confirm the presence of HIV-1 infection. CE-IVD: Same as above but in addition, this test can be used for confirmation of HIV-1 infection in antibody reactive individuals.
Principle of the assay	Real Time PCR.			
Target	HIV-1 (dual target LTR, gag)			
Genotypes and/ or subtypes	HIV-1 group M subtype A through H, CRF01_AE, group O, and group N	HIV-1 group M A-H, CRF01_AE	Group M (A-D, F-H, CRF01_AE, CRF02_AG), Group O, Group N	HIV-1M (A-D, F-H, CRF01_AE, CRF02_AG), HIV-1O, HIV-1N
Type of result	Qualitative	Quantitative		
Linear range	Not applicable	20 to 1.0E+07 cp/mL	400 µL: 20 copies/mL – 1.0 x 107 /mL 200 µL: 60 copies/mL – 1.0 x 107 /mL	500 µL: 20 copies/mL – 1 x 107 copies/mL 200 µL: 50 copies/mL – 1 x 107 copies/mL (200µL volume not commercially available in the United States)
Output	Not detected, detected	Quantitative viral load (cp/mL)		
DNA or RNA specific?	Total nucleic acid (TNA)	RNA		
Polyvalency	HBV VL, CMV VL, B*5701, Chlamydia trachomatis (COBAS TaqMan 48), Mycobaterium tuberculosis (COBAS TaqMan 48)		MRSA/SA, CT/NG, HPV, HSV.	HBV VL, CMV VL, RIF/INH, HPV, CT/NG
	PERFORMANCE			
Sensitivity - analytical and clinical (source)	100% (Instruction for use)	100% (Instruction for use)	400 µL: 20 copies/mL – 1.0 x 107 /mL 200 µL: 60 copies/mL – 1.0 x 107 /mL (Instructions For Use)	500 µL: 13.2 copies/mL 200 µL: 35.5 copies/mL (200µL volume not commercially available in the United States) (Instructions For Use)
Specificity - analytical and clinical (source)	99.8% Plasma 99.9% Dried Blood Spots (DBS) (Instruction for use)	100% (Instruction for use)	100% (one-sided confidence inverval: 99.5%) (Instructions For Use)	100% (one-sided confidence inverval: 99.5%) (Instructions For Use)
Bias (source)	Not provided.			

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Product	COBAS®AMPLIPREP/ COBAS® TAQMAN® HIV-1 QUALITATIVE TEST, VERSION 2.0	COBAS®AMPLIPREP/ COBAS® TAQMAN® HIV-1 TEST, VERSION 2.0	COBAS® HIV-1 FOR USE ON THE COBAS® 4800 SYSTEM	COBAS® HIV-1 FOR USE ON THE COBAS® 6800/8800 SYSTEMS
PERFORMANCE				
Intra-assay precision (source)	Not provided.			
Inter-assay precision (source)	Not provided.			
SAMPLE				
Sample preparation	Plasma: Patient samples have to be transferred to the Input S-tube (manually or with the use of the cobas p 630 Instrument) - from this point on, sample preparation is fully automated. DBS: pre-extraction protocol (manually) - from this point on, sample preparation is fully automated.	Patient samples have to be transferred to the Input S-tube (manually or with the use of the cobas p 630 Instrument) - from this point on, sample preparation is fully automated.	None	Centrifugation should be performed according to manufacturer instructions.
Sample type	Plasma, DBS	Plasma		Plasma or serum
Sample volume	Plasma: 1mL, 850uL are processed DBS: 1spot in 1000uL SPEX reagent, 850uL are processed	1mL (850mL gets processed)	400 µL or 200 µL	500 µL or 200 µL (200µL volume not commercially available in the United States)
Sample stability	Plasma specimens may be stored at room temperature (25-30°C) for ≤ 1 day, at 2°C - 8°C for ≤ 5 days or frozen at -20- -80°C for up to six weeks. DBS may be stored in individual re-sealable bags, with a dessicant sachet, at ambien temperature for ≤ 3 months.	Whole blood at 2-25°C for up to 24h Plasma at 25-30°C for up to 1 day Plasma at 2-8°C for up to 6 days Plasma at -20- -80°C for up to six weeks	Plasma samples may be stored in secondary tubes for up to 24 hours at 2°C to 25°C, up to 72 hours at 2°C to 8°C or up to 6 weeks at ≤ -18°C. Separated plasma/ serum samples in secondary tubes are stable for up to three freeze/thaw cycles when stored frozen at ≤ -18°C.	Plasma/serum samples may be stored in secondary tubes for up to 24 hours at 2°C to 25°C, up to 72 hours at 2°C to 8°C or up to 6 weeks at ≤ -18°C. Separated plasma/serum samples in secondary tubes are stable for up to three freeze/thaw cycles when stored frozen at ≤ -18°C.
Nucleic acid extraction method	Automated (docked and undocked options).			Automated
Time to result	5-8 hours		4 hours	First 96 results in less than 3.5 hrs and every 90 min 96 more results (cobas® 6800 System) and first 96 results in less than 3.5 hrs and every 30 min 96 more results (cobas® 8800 System)
Capacity	24 tests per batch (21 samples + 3 controls)		96 tests per batch (93 samples + 3 controls)	
Batching?	24 test per batch		96 tests per batch	
Throughput per end-user per hour and/or 8hr day	COBAS AmpliPrep: 144 sample extractions/ day COBAS TaqMan 48 Analyser: 48 samples/2.5-3.5h (test dependant) COBAS TaqMan Analyser: 96 samples/2.5-3.5h (test dependant) COBAS AmpliPrep Instrument can be connected via a dock to COBAS TaqMan for automated movement of samples		192 tests/8 hour	384 tests/8 hour (cobas® 6800 System) and 960 tests/8 hour (cobas® 8800 System)
INSTRUMENT				
Size of device	165 cm x 74.5 cm x 93.5 cm (Width x Depth x Height)		166.5 cm x 77.5 cm x 90.5 cm (Width x Depth x Height)	cobas® 6800 (Fixed): 292 cm x 129 cm x 216 cm (Width x Depth x Height) cobas® 6800 (Moveable): 292 cm x 129 cm x 222 cm (Width x Depth x Height) cobas® 8800: 429 cm x 129 cm x 216 cm (Width x Depth x Height)
Weight of device	310 kg		~180 kg	cobas® 6800 (Fixed): 1573 kg (Excluding instrument gateway server) and 1624 kg (Including instrument gateway server) cobas® 6800 (Moveable): 1701 kg (Excluding instrument gateway server) and 1752 kg (Including instrument gateway server) cobas® 8800: 2354 kg (Excluding instrument gateway server) and 2405 kg (Including instrument gateway server)

Product	COBAS AMPLIPREP/ COBAS TAQMAN HIV-1 QUALITATIVE TEST, V2.0	COBAS AMPLIPREP/ COBAS TAQMAN HIV-1 TEST, V2.0	COBAS AMPLIPREP/ COBAS TAQMAN HCV QUALITATIVE TEST, V2.0	COBAS AMPLIPREP/COBAS TAQMAN HCV TEST, V2.0
INSTRUMENT				
Robustness	Not provided			
Environmental requirements	Ambient room temperature (15 - 32 °C)			Ambient room temperature: 15°C to 28°C Relative humidity: 30% to 80% (no condensation) Air pressure: 80–106 kPa Altitude: <2000 m
Power requirements	Line voltage: 100-125 and 200-240 VAC (-15%, +10%) Line frequency: 50 or 60 Hz (±2 Hz) Power consumption: Max. 1,200 VA; Installation category II (EN/IEC 61010-1)		Line voltage: 115 VAC (-15%) to 230 VAC (+10%) Line frequency: 50 or 60 Hz (±5 Hz) Power consumption: Max. 600 VA	Line voltage: 200–240 VAC +/- 10% Line frequency: 50/60 Hz +/- 5% Maximum power: 3500 VA Insulation coordination: Installation Category II (IEC 61010-1)
Time to battery charge	N/A			
Battery duration	N/A			
Alternative charging options	None			
Ease of use	Data Station		Not provided	
Display languages	English			
Built-in memory capacity	Not provided			
Connectivity options	Yes			Yes. LIS connectivity: Uni- and bi-directional communication using HL7 standard protocol
Interpretation of result	Automatic interpretation of data			
Instrument lifespan	Depends on number of samples run			
Other non-proprietary equipment required	Vortex mixer			
Regulatory approval	WHO-PQ, CE-IVD	WHO-PQ, CE-IVD, US-IVD	CE-IVD	CE-IVD, US-IVD, Canada-IVD, Japan-IVD, among others.
KIT				
Kit components	COBAS AmpliPrep/COBAS TaqMan HIV-1 Qualitative Test, v2.0 COBAS AmpliPrep/COBAS TaqMan Wash Reagent 1 x 5.1 L	COBAS AmpliPrep/COBAS TaqMan HIV-1 Test, v2.0 COBAS AmpliPrep/COBAS TaqMan Wash Reagent 1 x 5.1 L	- cobas® HIV-1 - cobas® HBV/HCV/HIV-1 Control Kit - cobas® 4800 System Sample Preparation Kit 2 - cobas® 4800 System Wash Buffer Kit - cobas® 4800 System Specimen Diluent 2 - cobas® 4800 System Lysis Kit 2	- cobas® HIV-1 - cobas® HBV/HCV/HIV-1 Control Kit - cobas® NHP Negative Control Kit - cobas omni Lysis Reagent - cobas omni MGP Reagent - cobas omni Specimen Diluent- XX - cobas omni Wash Reagent
Kit sizes	48 tests/kit		120 tests/kit	96 tests/kit
Internal control(s)	Yes		- cobas® HBV/HCV/HIV-1 Low Positive Control - cobas® HBV/HCV/HIV-1 High Positive Control - cobas® Negative Control 2	- cobas® HBV/HCV/HIV-1 Low Positive Control - cobas® HBV/HCV/HIV-1 High Positive Control - cobas® NHP Negative Control Kit
Compatible with EQA and which?	Yes: QCMD		Not provided	
Mean time between failures	COBAS AmpliPrep Instrument: 125 days COBAS TaqMan Analyser: 276 days COBAS TaqMan 48 Analyser: 902 days		Not provided	
Transport and storage	Reagents: 2-8ºC Disposables: room temperature			
Fridge at -80°C required?	No			

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Product	COBAS AMPLIPREP/ COBAS TAQMAN HIV-1 QUALITATIVE TEST, V2.0	COBAS AMPLIPREP/ COBAS TAQMAN HIV-1 TEST, V2.0	COBAS AMPLIPREP/ COBAS TAQMAN HCV QUALITATIVE TEST, V2.0	COBAS AMPLIPREP/COBAS TAQMAN HCV TEST, V2.0
KIT				
Shelf life (of each item in the kit)	Average 6 months, dependant on earliest expiry of components.			
Performance protocol (steps)	As per Instructions for Use.			
Non-proprietary components required outside of the kit	As per Instructions for Use.			
Regulatory approval	WHO-PQ, CE-IVD			CE-IVD, US-IVD
In-country approvals	Not provided.			
USAGE				
Technical skill required	Medium-highly trained, precision pipetting required.			
Applicable settings	Low- to highly-resourced settings.			
Laboratory set-up	Specialized; 1 dedicated area required for the COBAS AmpliPrep/COBAS TaqMan with docking station; preferably 2 dedicated areas for the COBAS AmpliPrep/ COBAS TaqMan 48 System option.		Not provided	
Waste disposal requirements	According to individual country regulations.			

	HCV VIRAL LOAD			
Company	**Roche Molecular Systems**			
Product	**COBAS®AMPLIPREP/ COBAS® TAQMAN® HCV QUALITATIVE TEST, VERSION 2.0**	**COBAS®AMPLIPREP/ COBAS® TAQMAN® HCV QUANTITATIVE TEST, VERSION 2.0**	**COBAS® HCV - QUANTITATIVE NUCLEIC ACID TEST FOR USE ON THE COBAS® 4800 SYSTEM**	**COBAS® HCV - QUANTITATIVE NUCLEIC ACID TEST FOR USE ON THE COBAS® 6800/8800 SYSTEM**
ASSAY				
Intended use	Qualitative in vitro nucleic acid amplification test for the detection of HCV RNA genotypes 1 to 6 The test is indicated for patients who have clinical and/or biochemical evidence of liver disease and antibody evidence of HCV infection, and who are suspected to be actively infected with HCV. The test can be used to confirm antibody positive specimens. Detection of HCV RNA indicates that the virus is replicating and therefore is evidence of active infection. The test is not intended for use as a screening test for the presence of HCV in blood or blood products.	In vitro nucleic acid amplification test for the quantitation of HCV RNA genotypes 1 to 6. The test is intended for use in the management of patients with chronic HCV in conjunction with clinical and laboratory markers of infection. The test can be used to predict the probability of sustained virologic response (SVR) early during a course of antiviral therapy, and to assess viral response to antiviral treatment as measured by changes of HCV RNA levels. The test is not intended for use as a screening test for the presence of HCV in blood or blood products or as a diagnostic test to confirm the presence of HCV infection.	In vitro nucleic acid amplification test for both the detection and quantitation of HCV RNA. Specimens containing HCV genotype 1 to 6 are validated for detection and quantitation in the assay. The test is intended for use as an aid in the diagnosis of HCV infection in the following populations: individuals with antibody evidence of HCV with evidence of liver disease, individuals suspected to be actively infected with HCV antibody evidence, and individuals at risk for HCV infection with antibodies to HCV. Detection of HCV RNA indicates that the virus is replicating and therefore is evidence of active infection. The test is intended for use as an aid in the management of HCV-infected patients undergoing anti-viral therapy. The assay measures HCV RNA levels at baseline and during treatment and can be utilized to predict sustained and non-sustained virological response to HCV therapy. The results must be interpreted within the context of all relevant clinical and laboratory finding.	In vitro nucleic acid amplification test for both the detection and quantitation of HCV RNA genotypes 1 to 6.The test is intended for use as an aid in the diagnosis of HCV infection in the following populations: individuals with antibody evidence of HCV with evidence of liver disease, individuals suspected to be actively infected with HCV antibody evidence, and individuals at risk for HCV infection with antibodies to HCV. Detection of HCV RNA indicates that the virus is replicating and therefore is evidence of active infection. The test is intended for use in the management of patients with chronic HCV in conjunction with clinical and laboratory markers of infection. The test can be used to predict the probability of sustained virologic response (SVR) early during a course of antiviral therapy, and to assess viral response to antiviral treatment as measured by changes of HCV RNA levels. The results must be interpreted within the context of all relevant clinical and laboratory finding.

Product	COBAS®AMPLIPREP/ COBAS® TAQMAN® HCV QUALITATIVE TEST, VERSION 2.0	COBAS®AMPLIPREP/ COBAS® TAQMAN® HCV QUANTITATIVE TEST, VERSION 2.0	COBAS® HCV - QUANTITATIVE NUCLEIC ACID TEST FOR USE ON THE COBAS® 4800 SYSTEM	COBAS® HCV - QUANTITATIVE NUCLEIC ACID TEST FOR USE ON THE COBAS® 6800/8800 SYSTEM
ASSAY				
Principle of the assay	Real Time PCR.			
Target	5'UTR			
Genotypes and/ or subtypes	Genotypes 1 tp 6			
Type of result	Qualitative	Quantitative		
Linear range	N/A	15 - 100,000,000 IU/mL	400 µL: 15 IU/mL – 1 x 108 IU/mL	500 µL: 15 IU/mL – 1.0E+08 IU/mL
Output	Qualitative: Not deteceted, detected	Quantitative viral load result expressed in International Units per milliliter (IU/mL).		
DNA or RNA specific?	RNA			
Polyvalency	HBV VL, CMV VL, B*5701, Chlamydia trachomatis (COBAS TaqMan 48), Mycobaterium tuberculosis (COBAS TaqMan 48)		MRSA/SA, CT/NG, HPV, HSV.	HBV VL, CMV VL, RIF/INH, HPV, CT/ NG
PERFORMANCE				
Sensitivity - analytical and clinical (source)	100% (Instruction for use)	100% (Instruction for use)	400 µL (plasma): 9.2 IU/mL (95% confidence range: 7.8–11.5 IU/mL) 200 µL (plasma): 15.3 IU/mL (95% confidence range: 13.1–18.5 IU/mL) 400 µL (serum): 7.6 IU/mL (95% confidence range: 6.5–9.5 IU/mL) 200 µL (serum): 15.3 IU/mL (95% confidence range: 13.1–18.7 IU/mL) (Instructions For Use)	15 IU/mL (500 µL) 40 IU/mL (200 µL) (Instructions For Use)
Specificity - analytical and clinical (source)	Plasma or serum: 99.8% (Instruction for use)	Plasma or serum: 100% (Instruction for use)	99.5 % (95% confidence limit: ≥ 98.7%) (Instructions For Use)	100% (one-sided confidence inverval: 99.5%) (Instructions For Use)
Bias (source)	Not provided.			
Intra-assay precision (source)	Not provided.			
Inter-assay precision (source)	Not provided.			
SAMPLE				
Sample preparation	Patient samples have to be transferred to the Input S-tube (manually or with the use of the cobas p 630 Instrument) - from this point on, sample preparation is fully automated.	Patient samples have to be transferred to the Input S-tube (manually or with the use of the cobas p 630 Instrument) - from this point on, sample preparation is fully automated.	None	Centrifugation should be performed according to manufacturer instructions.
Sample type	Plasma or serum			
Sample volume	1mL (650uL are processed)	1mL (850mL gets processed)	400 µL or 200 µL	500 µL or 200 µL
Sample stability	Plasma or serum specimens may be stored at at 2°C - 8°C for ≤ 3 days or frozen at -20 to -80°C for ≤ six weeks.	Plasma or serum specimens may be stored at at 4°C for ≤ 3 days or frozen at -20 to -80°C for ≤ six weeks.	Plasma or serum samples may be stored in secondary tubes for up to 24 hours at 2°C to 25°C, up to 72 hours at 2°C to 8°C or up to 6 weeks at ≤ -18°C. Separated plasma/serum samples in secondary tubes are stable for up to three freeze/thaw cycles when stored frozen at ≤ -18°C.	Plasma/serum samples may be stored in secondary tubes for up to 24 hours at 2°C to 25°C, up to 72 hours at 2°C to 8°C or up to 6 weeks at ≤ -18°C. Separated plasma/serum samples in secondary tubes are stable for up to three freeze/thaw cycles when stored frozen at ≤ -18°C.
Nucleic acid extraction method	Automated (docked and undocked options).		Automated	
Time to result	5-8 hours		4 hours	First 96 results in less than 3.5 hrs and every 90 min 96 more results (cobas® 6800 System) and first 96 results in less than 3.5 hrs and every 30 min 96 more results (cobas® 8800 System)

Product	COBAS®AMPLIPREP/ COBAS® TAQMAN® HCV QUALITATIVE TEST, VERSION 2.0	COBAS®AMPLIPREP/ COBAS® TAQMAN® HCV QUANTITATIVE TEST, VERSION 2.0	COBAS® HCV - QUANTITATIVE NUCLEIC ACID TEST FOR USE ON THE COBAS® 4800 SYSTEM	COBAS® HCV - QUANTITATIVE NUCLEIC ACID TEST FOR USE ON THE COBAS® 6800/8800 SYSTEM
SAMPLE				
Capacity	24 tests per batch (21 samples + 3 controls)		96 tests per batch (93 samples + 3 controls)	
Batching?	Yes. System can perform additional batches with its interleaved capability.		Yes. The run can be HCV only, or in mixed-batch format with tests that share the same automated specimen extraction process and PCR profile for amplification and detection.	Yes, batches of 96 tests, with up to 3 assays per batch.
Throughput per end-user per hour and/or 8hr day	COBAS AmpliPrep: 144 sample extractions/ day COBAS TaqMan 48 Analyser: 48 samples/2.5-3.5h (test dependant) COBAS TaqMan Analyser: 96 samples/2.5-3.5h (test dependant) COBAS AmpliPrep Instrument can be connected via a dock to COBAS TaqMan for automated movement of samples		192 tests/8 hour	384 tests/8 hour (cobas® 6800 System) and 960 tests/8 hour (cobas® 8800 System)
INSTRUMENT				
Size of device	165 cm x 74.5 cm x 93.5 cm (Width x Depth x Height)		166.5 cm x 77.5 cm x 90.5 cm (Width x Depth x Height)	cobas® 6800 (Fixed): 292 cm x 129 cm x 216 cm (Width x Depth x Height) cobas® 6800 (Moveable): 292 cm x 129 cm x 222 cm (Width x Depth x Height) cobas® 8800: 429 cm x 129 cm x 216 cm (Width x Depth x Height)
Weight of device	310 kg		~180 kg	cobas® 6800 (Fixed): 1573 kg (Excluding instrument gateway server) and 1624 kg (Including instrument gateway server) cobas® 6800 (Moveable): 1701 kg (Excluding instrument gateway server) and 1752 kg (Including instrument gateway server) cobas® 8800: 2354 kg (Excluding instrument gateway server) and 2405 kg (Including instrument gateway server)
Robustness	Not provided			
Environmental requirements	Ambient room temperature (15 - 32 °C)			Ambient room temperature: 15°C to 28°C Relative humidity: 30% to 80% (no condensation) Air pressure: 80–106 kPa Altitude: <2000 m
Power requirements	Line voltage: 100-125 and 200-240 VAC (-15%, +10%) Line frequency: 50 or 60 Hz (±2 Hz) Power consumption: Max. 1,200 VA; Installation category II (EN/IEC 61010-1)		Line voltage: 115 VAC (-15%) to 230 VAC (+10%) Line frequency: 50 or 60 Hz (±5 Hz) Power consumption: Max. 600 VA	Line voltage: 200–240 VAC +/- 10% Line frequency: 50/60 Hz +/- 5% Maximum power: 3500 VA Insulation coordination: Installation Category II (IEC 61010-1)
Time to battery charge	N/A			
Battery duration	N/A			
Alternative charging options	None			
Ease of use	Data Station		Not provided	
Display languages	English			
Built-in memory capacity	Not provided			
Connectivity options	Yes			Yes. LIS connectivity: Uni- and bi-directional communication using HL7 standard protocol
Interpretation of result	Automatic interpretation of data			
Instrument lifespan	Depends on number of samples run			
Other non-proprietary equipment required	Vortex mixer			
Regulatory approval	CE-IVD, US-IVD	CE-IVD, US-IVD	CE-IVD, US-IVD	CE-IVD, US-IVD, Canada-IVD, Japan-IVD, among others.

Product	COBAS®AMPLIPREP/ COBAS® TAQMAN® HCV QUALITATIVE TEST, VERSION 2.0	COBAS®AMPLIPREP/ COBAS® TAQMAN® HCV QUANTITATIVE TEST, VERSION 2.0	COBAS® HCV - QUANTITATIVE NUCLEIC ACID TEST FOR USE ON THE COBAS® 4800 SYSTEM	COBAS® HCV - QUANTITATIVE NUCLEIC ACID TEST FOR USE ON THE COBAS® 6800/8800 SYSTEM
KIT				
Kit components	COBAS AmpliPrep/COBAS TaqMan HCV Qualitative Test, v2.0 COBAS AmpliPrep/ COBAS TaqMan Wash Reagent 1 x 5.1 L	COBAS AmpliPrep/COBAS TaqMan HCV Quantitative Test, v2.0 COBAS AmpliPrep/ COBAS TaqMan Wash Reagent 1 x 5.1 L	- cobas® HCV - cobas® HBV/HCV/HIV-1 Control Kit - cobas® 4800 System Sample Preparation Kit 2 - cobas® 4800 System Wash Buffer Kit - cobas® 4800 System Specimen Diluent 2 - cobas® 4800 System Lysis Kit 2	- cobas® HCV - cobas® HBV/HCV/HIV-1 Control Kit - cobas® NHP Negative Control Kit - cobas omni Lysis Reagent - cobas omni MGP Reagent - cobas omni Specimen Diluent- XX - cobas omni Wash Reagent
Kit sizes	72 tests/kit		120 tests/kit	96 tests/kit
Internal control(s)	Yes. Quantitation Standard		- cobas® HBV/HCV/HIV-1 Low Positive Control - cobas® HBV/HCV/HIV-1 High Positive Control - cobas® Negative Control 2	- cobas® HBV/HCV/HIV-1 Low Positive Control - cobas® HBV/HCV/HIV-1 High Positive Control - cobas® NHP Negative Control Kit
Compatible with EQA and which?	Yes: QCMD		Not provided	
Mean time between failures	COBAS AmpliPrep Instrument: 125 days COBAS TaqMan Analyser: 276 days COBAS TaqMan 48 Analyser: 902 days	COBAS AmpliPrep Instrument: 114 days COBAS TaqMan Analyser: 236 days COBAS TaqMan 48 Analyser: 850 days	Not provided	
Transport and storage	Reagents: 2-8ºC Disposables: room temperature			
Fridge at -80°C required?	No			
Shelf life (of each item in the kit)	Average 6 months, dependant on earliest expiry of components.			
Performance protocol (steps)	As per Instructions for Use.			
Non-proprietary components required outside of the kit	As per Instructions for Use.			
Regulatory approval	CE-IVD	CE-IVD, US-IVD	CE-IVD	CE-IVD, US-IVD
In-country approvals	Not provided.			
USAGE				
Technical skill required	Medium-highly trained, precision pipetting required.			
Applicable settings	Low- to highly-resourced settings.			
Laboratory set-up	Specialized; 1 dedicated area required for the COBAS AmpliPrep/COBAS TaqMan with docking station; preferably 2 dedicated areas for the COBAS AmpliPrep/ COBAS TaqMan 48 System option.		Not provided	
Waste disposal requirements	According to individual country regulations.			

	HCV GENOTYPING				
Company	**ROCHE MOLECULAR SYSTEMS**		**Product**	**COBAS® HCV GT**	
ASSAY		**SAMPLE**		**KIT**	
Intended use	In vitro nucleic acid amplification test for the qualitative identification of HCV genotypes 1 to 6 and genotype 1 subtypes a and b in individuals with chronic HCV infection. The test is intended for use in selecting individuals with chronic HCV infection for antiviral therapy and in determining the duration of therapy regimens according to the antiviral therapy prescribing information.	**Nucleic acid extraction method**	Automated	**Kit components**	Test, controls, sample prepation kit, wash buffer, and lysis kit
		Time to result	4 hours		
		Capacity	96 tests per batch (93 samples + 3 controls)	**Kit sizes**	120 tests
		Batching?	Yes. The run can be HCV GT only, or in mixed-batch format.	**Internal control(s)**	- cobas® HCV GT Positive Control - cobas® Negative Control
Principle of the assay	Real Time RT-PCR	**Throughput per end-user per hour and/ or 8hr day**	96 tests / 8 hour	**Compatible with EQA and which?**	Not provided
Target	Three different target regions in the HCV genome (5'-UTR, Core, NS5B)			**Mean time between failures**	Not provided
Genotypes and/or subtypes	HCV genotypes 1 – 6 and genotype 1 subtypes a and b	**INSTRUMENT**		**Transport and storage**	Reagents: 2-8ºC. Disposables: room temperature
Type of result	Quantitative	**Size of device**	166.5 cm x 77.5 cm x 90.5 cm (Width x Depth x Height)		
Linear range	N/A	**Weight of device**	~180 kg	**Fridge at -80°C required?**	No
Output	The cobas® 4800 System automatically determines the HCV genotype and subtype 1a and 1b for the specimens.	**Robustness**	Not provided	**Shelf life (of each item in the kit)**	Average 6 months, dependant on earliest expiry of components.
		Environmental requirements	Ambient room temperature (15 - 32 °C)		
DNA or RNA specific?	RNA	**Power requirements**	Line voltage: 115 VAC (-15%) to 230 VAC (+10%) Line frequency: 50 or 60 Hz (±5 Hz) Power consumption: Max. 600 VA	**Performance protocol (steps)**	As per instructions for use.
Polyvalency	MRSA/SA, CT/NG, HPV, HSV.			**Non-proprietary components required outside of the kit**	None
PERFORMANCE		**Time to battery charge**	N/A		
Sensitivity - analytical and clinical (source)	Not provided	**Battery duration (hours)**	N/A		
Specificity - analytical and clinical (source)		**Alternative charging options**	Not provided	**Regulatory approval**	CE-IVD
Bias (source)		**Ease of use**	Not provided		
Intra-assay precision (source)		**Display languages**	English	**In-country approvals**	Not provided
Inter-assay precision (source)		**Built-in memory storage capacity**	Not provided	**USAGE**	
SAMPLE				**Technical skill required**	Medium-highly trained, precision pipetting needed
Sample preparation	None	**Connectivity options**	Yes		
Sample type	Plasma or serum	**Interpretation of result**	Automatic interpretation of data	**Applicable settings**	Low- to highly resourced settings
Sample volume	400 µL				
Sample stability	Samples may be stored in secondary tubes for up to 24 hours at 2°C to 25°C, up to 72 hours at 2°C to 8°C or up to 6 weeks at ≤ -18°C. Separated samples in secondary tubes are stable for up to three freeze/thaw cycles when stored frozen at ≤ -18°C.	**Instrument lifespan**	Depends on number of samples run	**Laboratory set-up**	Not provided
		Other non-proprietary equipment required	Vortex mixer	**Waste disposal requirements**	According to individual country regulations.
		Regulatory approval	CE-IVD		

02 | PRICING

HIV EARLY INFANT DIAGNOSIS						
Instrument		**Reference number**	**FCA ($)**	**Cartridge/reagents**	**Reference number**	**FCA ($)**
COBAS AmpliPrep / COBAS TaqMan Systems	Sample preparation, amplification and detection	3051315001 and 3121453001	$150,000*	COBAS AmpliPrep/COBAS TaqMan HIV-1 Qualitative Test, v2.0	6693083190	
				COBAS AmpliPrep/COBAS TaqMan Wash Reagent 1 x 5.1 L	3587797190	
				COBASAmpliPrep/COBAS TaqMan Specimen Pre-Extraction Reagent	6989861190	
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**	**Reference number**	**FCA ($)**
Tube-K Box of 12x96/Cob.TaqMan		3137082001		None		
SPU of 12x24/Cob.AmpliP		3155525001				
Tube-S Box of 12x24/Cob.AmpliP		3137040001				
Tip-K 1,2 mm ID Box of 12x36		3287343001				
Price per instrument			**$150,000***	**Price per test result**		**$9.40***

* Price based on Global Access Pricing for eligible countries

HIV VIRAL LOAD (COBAS AmpliPrep / COBAS® TaqMan Systems)						
Instrument		**Reference number**	**FCA ($)**	**Cartridge/reagents**	**Reference number**	**FCA ($)**
COBAS AmpliPrep / COBAS TaqMan Systems	Sample preparation, amplification and detection	3051315001 and 3121453001	$150,000*	COBAS AmpliPrep/COBAS TaqMan HIV-1 Test, v2.0		
				COBAS AmpliPrep/COBAS TaqMan Wash Reagent 1 x 5.1 L		
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**	**Reference number**	**FCA ($)**
Tube-K Box of 12x96/Cob.TaqMan		3137082001	$80	None		
SPU of 12x24/Cob.AmpliP		3155525001	$93			
Tube-S Box of 12x24/Cob.AmpliP		3137040001	$90			
Tip-K 1,2 mm ID Box of 12x36		3287343001	$55			
Price per instrument			**$150,000***	**Price per test result**		**$9.40**

* Price based on Global Access Pricing for eligible countries

HIV VIRAL LOAD (cobas 4800 System)						
Instrument		**Reference number**	**FCA ($)**	**Cartridge/reagents**	**Reference number**	**FCA ($)**
cobas x 480 Instrument	Sample preparation	5200890001	$150,000*	cobas HIV-1	6979599190	
cobas z 480 Analyzer	Amplification and detection	5200881001		cobas HBV/HCV/HIV-1 Control Kit	6979572190	
				cobas 4800 System Sample Preparation Kit 2 (240 tests)	6979513190	
				cobas 4800 System Sample Preparation Kit 2 (960 tests)	6979521190	
				cobas 4800 System Wash Buffer Kit (240 Tests)	5235863190	
				cobas 4800 System Wash Buffer Kit (960 Tests)	5235871190	
				cobas 4800 System Specimen Diluent 2	6979556190	
				cobas 4800 System Lysis Kit 2 (240 Tests)	6979530190	
				cobas 4800 System Lysis Kit 2 (240 Tests)	6979548190	
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**	**Reference number**	**FCA ($)**
cobas® 4800 System Extraction (deepwell) Plate 2.0 mL		6884008001		None		
cobas® 4800 System AD (microwell) Plate 0.3 mL		5232724001				
Sealing foil applicator		4900383001				
CORE Tips, 1000 µL, rack of 96		4639642001				
200 mL Reagent Reservoir		5232759001				
50 mL Reagent Reservoir		5232732001				
24-position carrier		4639502001				
32-position carrier		4639529001				
Solid waste bag		5530873001				
Price per instrument			**$150,000***	**Price per test result**		**$9.40***

* Price based on Global Access Pricing for eligible countries

HIV VIRAL LOAD (cobas 6800/8800 system)

Instrument		Reference number	FCA ($)	Cartridge/reagents	Reference number	FCA ($)
cobas® 6800 System (Option Moveable)		05524245001 and 06379672001	$340,000*	cobas HIV-1	7000995190	
cobas® 6800 System (Fix)		05524245001 and 06379664001	$360,000*	cobas HBV/HCV/HIV-1 Control Kit	6998887190	
cobas® 8800 System		5412722001	$475,000*	cobas® NHP Negative Control Kit	7002220190	
				cobas omni Lysis Reagent	6997538190	
				cobas omni MGP Reagent	6997546190	
				cobas omni Specimen Diluent- XX	6997511190	
				cobas omni Wash Reagent	6997503190	
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**	**Reference number**	**FCA ($)**
cobas omni Processing Plate		5534917001		None		
cobas omni Amplification Plate		5534941001				
cobas omni Pippette Tips		5534925001				
cobas omni Liquid Waste Container		7094388001				
cobas omni Lysis Reagent		6997538190				
cobas omni MGP Reagent		6997546190				
cobas omni Specimen diluent		6997511190				
cobas omni Wash Reagent		6997503190				
Solid Waste Bag		7435967001				
Solid Waste Container		7094361001				
Price per instrument			**$340,000 to 475,000****	**Price per test result**		**$9.40***

* Price based on Global Access Pricing for eligible countries
** Depends on the instrument.

HCV QUALITATIVE

Instrument		Reference number	FCA ($)	Cartridge/reagents	Reference number	FCA ($)
COBAS AmpliPrep / COBAS TaqMan Systems	Sample preparation, amplification and detection	3051315001 and 3121453001	$150,000*	COBAS AmpliPrep/COBAS TaqMan HCV Qualitative Test, v2.0	5480477190	
				COBAS AmpliPrep/COBAS TaqMan Wash Reagent 1 x 5.1 L	3587797190	
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**	**Reference number**	**FCA ($)**
Tube-K Box of 12x96/Cob.TaqMan		3137082001		None		
SPU of 12x24/Cob.AmpliP		3155525001				
Tube-S Box of 12x24/Cob.AmpliP		3137040001				
Tip-K 1,2 mm ID Box of 12x36		3287343001				
Price per instrument			**$150,000***	**Price per test result**		**$45#**

* Price based on Global Access Pricing for eligible countries
# Indicative price. Price will depend on volume commitments.

HCV VIRAL LOAD						
Instrument		**Reference number**	**FCA ($)**	**Cartridge/reagents**	**Reference number**	**FCA ($)**
COBAS AmpliPrep / COBAS TaqMan Systems	Sample preparation, amplification and detection	3051315001 and 3121453001	$150,000*	COBAS AmpliPrep/COBAS TaqMan HCV Quantitative Test, v2.0	5532264190	
				COBAS AmpliPrep/COBAS TaqMan Wash Reagent 1 x 5.1 L	3587797190	
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**	**Reference number**	**FCA ($)**
Tube-K Box of 12x96/Cob.TaqMan		3137082001		None		
SPU of 12x24/Cob.AmpliP		3155525001				
Tube-S Box of 12x24/Cob.AmpliP		3137040001				
Tip-K 1,2 mm ID Box of 12x36		3287343001				
Price per instrument			**$150,000***	**Price per test result**		**$45#**

* Price based on Global Access Pricing for eligible countries
# Indicative price. Price will depend on volume commitments.

HCV VIRAL LOAD (cobas 4800 System)						
Instrument		**Reference number**	**FCA ($)**	**Cartridge/reagents**	**Reference number**	**FCA ($)**
cobas x 480 Instrument	Sample preparation	5200890001	$150,000*	cobas HCV	6979602190	
cobas z 480 Analyzer	Amplification and detection	5200881001		cobas HBV/HCV/HIV-1 Control Kit	6979572190	
				cobas 4800 System Sample Preparation Kit 2 (240 tests)	6979513190	
				cobas 4800 System Sample Preparation Kit 2 (960 tests)	6979521190	
				cobas 4800 System Wash Buffer Kit (240 Tests)	5235863190	
				cobas 4800 System Wash Buffer Kit (960 Tests)	5235871190	
				cobas 4800 System Specimen Diluent 2	6979556190	
				cobas 4800 System Lysis Kit 2 (240 Tests)	6979530190	
				cobas 4800 System Lysis Kit 2 (960 Tests)	6979548190	
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**	**Reference number**	**FCA ($)**
cobas® 4800 System Extraction (deepwell) Plate 2.0 mL		6884008001		None		
cobas® 4800 System AD (microwell) Plate 0.3 mL		5232724001				
Sealing foil applicator		4900383001				
CORE Tips, 1000 µL, rack of 96		4639642001				
200 mL Reagent Reservoir		5232759001				
50 mL Reagent Reservoir		5232732001				
24-position carrier		4639502001				
32-position carrier		4639529001				
Solid waste bag		5530873001				
Price per instrument			**$150,000***	**Price per test result**		**$35#**

* Price based on Global Access Pricing for eligible countries
# Indicative price. Price will depend on volume commitments.

HCV VIRAL LOAD (cobas 6800/8800 system)

Instrument		Reference number	FCA ($)	Cartridge/reagents	Reference number	FCA ($)
cobas® 6800 System (Option Moveable)		05524245001 and 06379672001	$340,000*	cobas HCV	6998798190	
cobas® 6800 System (Fix)		05524245001 and 06379664001	$360,000*	cobas HBV/HCV/HIV-1 Control Kit	6998887190	
cobas® 8800 System		5412722001	$475,000*	cobas® NHP Negative Control Kit	7002220190	
				cobas omni Lysis Reagent	6997538190	
				cobas omni MGP Reagent	6997546190	
				cobas omni Specimen Diluent- XX	6997511190	
				cobas omni Wash Reagent	6997503190	
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**	**Reference number**	**FCA ($)**
cobas omni Processing Plate		5534917001		None		
cobas omni Amplification Plate		5534941001				
cobas omni Pippette Tips		5534925001				
cobas omni Liquid Waste Container		7094388001				
cobas omni Lysis Reagent		6997538190				
cobas omni MGP Reagent		6997546190				
cobas omni Specimen diluent		6997511190				
cobas omni Wash Reagent		6997503190				
Solid Waste Bag		7435967001				
Solid Waste Container		7094361001				
Price per instrument			**$340,000 to 475,000****	**Price per test result**		**$35#**

* Price based on Global Access Pricing for eligible countries. ** Depends on the instrument. # Indicative price. Price will depend on volume commitments.

HCV GENOTYPING (cobas 4800 System)

Instrument		Reference number	FCA ($)	Cartridge/reagents	Reference number	FCA ($)
cobas x 480 Instrument	Sample preparation	5200890001	$150,000*	cobas HCV	6984274190	
cobas z 480 Analyzer	Amplification and detection	5200881001		cobas HCV GT Control Kit	6984339190	
				cobas 4800 System Sample Preparation Kit 2 (240 tests)	6979513190	
				cobas 4800 System Sample Preparation Kit 2 (960 tests)	6979521190	
				cobas 4800 System Wash Buffer Kit (240 Tests)	5235863190	
				cobas 4800 System Wash Buffer Kit (960 Tests)	5235871190	
				cobas 4800 System Specimen Diluent 2	6979556190	
				cobas 4800 System Lysis Kit 2 (240 Tests)	6979530190	
				cobas 4800 System Lysis Kit 2 (960 Tests)	6979548190	
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**	**Reference number**	**FCA ($)**
cobas® 4800 System Extraction (deepwell) Plate 2.0 mL		6884008001		None		
cobas® 4800 System AD (microwell) Plate 0.3 mL		5232724001				
Sealing foil applicator		4900383001				
CORE Tips, 1000 µL, rack of 96		4639642001				
200 mL Reagent Reservoir		5232759001				
50 mL Reagent Reservoir		5232732001				
24-position carrier		4639502001				
32-position carrier		4639529001				
Solid waste bag		5530873001				
Price per instrument			**$150,000***	**Price per test result**		**$35#**

* Price based on Global Access Pricing for eligible countries. # Indicative price. Price will depend on volume commitments.

03 | TIERED AND VOLUME-BASED PRICING

Price will depend on country income level and volume commitments.

04 | MAINTENANCE, WARRANTY & TRAINING

	Description
Leasing or reagent rental (RAP)	Outright purchase, leasing and rental are available dependent on country, contractual volume commitment with mitigation risk assessment.
Installation	Yes, included in acquisition cost.
Training	Yes, included in acquisition cost.
Maintenance (including instrument swap)	Information not provided.
Length(s) of warranty and additional costs for extended warranty / care plan	Standard Manufacture Warranty (12 months): includes parts, travel and labour. Extended Warranty (months 13-24): up to 2 preventive maintenance visits. Excludes break down and repair visits.
Warranty components	Parts, travel and labour.
Turnkey option	Information not provided.
in-country / regional technical support availability	Roche provides in-country/regional technical support either directly through Roche or by a Roche distributor.

05 | CONTACT INFO

Ana dos Santos
International Business Leader / Virology

4300 Hacienda Drive
Pleasanton,CA 94588 USA

Website: molecular.roche.com
Tel: +1 925 730 8871
Mobile: +1 925 399 9176
Email: ana.dos_santos@roche.com

COBAS 4800

COBAS 6800

COBAS 8800

LAB-BASED HIV VL, HCV VL & HCV GT
SACACE BIOTECHNOLOGIES

01 | TECHNICAL AND PERFORMANCE INFORMATION

	HIV VIRAL LOAD	HCV VIRAL LOAD	HCV GENOTYPE
Company	**Sacace Biotechnologies**		
Product	**HIV REAL-TM QUANT DX**	**HCV REAL-TM QUANT DX**	**HCV GENOTYPE PLUS REAL-TM**
ASSAY			
Intended use (as per regulatory approval)	Quantitative detection of HIV-1 RNA. Provides prognostic information regarding likelihood of treatment response to antiretroviral therapy.	Quantitative detection of HCV RNA. Provides prognostic information regarding likelihood of treatment response to interferon monotherapy, interferon plus ribavirin combination therapy and peginterferon plus ribavirin combination therapy.	Genotyping of HCV virus genotypes 1-6.
Principle of the assay	Quantitative Real-Time PCR using fluorescently-labelled probes and dual colour detection.	Quantitative Real-Time PCR using fluorescently-labelled probes and dual colour detection.	Real time PCR with 2-channel fluorescent detection.
Target	Pol	5'UTR region	
Genotypes and/ or subtypes	All relevant genotypes: all subtypes of HIV-1 M-group (A, B, C, D, AE, F, G, AA-GH)	1a, 1b, 2, 3, 4, 5a, 6	
Type of result	Quantitative		Genotype
Linear range	48 - 10,000,000 IU/mL	13 - 10,000,000 IU/mL	N/A
Output	Viral load		Genotype
DNA or RNA specific?	RNA specific		
Polyvalency	Not provided		
PERFORMANCE			
Sensitivity - analytical and clinical (source)	48 IU/mL with 1.0 mL sample	13 IU/mL with 1.0 mL sample	1,000 IU/mL
Specificity - analytical and clinical (source)	100%	100%	100%
Bias (source)	Not provided		
Intra-assay precision (source)	CV % = 0.71	CV % = 0.86	N/A
Inter-assay precision (source)	CV % = 0.82	CV % = 1.37	N/A
SAMPLE			
Sample preparation (steps)	Whole blood collected in EDTA should be separated into plasma and cellular components by centrifugation at 800-1,600 x g for 20 min within six hours. The isolated plasma has to be transferred into a sterile polypropylene tube.		
Sample type	Plasma		
Sample volume	100 - 1,000 µL		
Sample stability	Plasma may be stored at 2-8°C for an additional 3 days. Alternatively, plasma may be stored at -18°C for up to one month or 1 year when stored at -70°C.		
Nucleic acid extraction method	Automatic or manual. Any commercial RNA/DNA isolation kit, if CE-IVD validated for viral nucleic acids extraction from plasma, could be used. Manual: Sacace MagnoVirus Automated: Sacace SaMag Nucleic Acids Automatic Extractor		Automated or manual. Manual (any nucleic acid extraction kit; Sacace recommend their own one) or automated (e.g. NucliSens easyMAG (bioMérieux)).
Time to result	3 hours		
Capacity	96 samples per run		
Batching?	96 samples per plate		
Throughput per end-user per hour and/or 8hr day	96 samples per day using SaMag automatic nucleic acid extractor.		50 samples per day.

Product	HIV REAL-TM QUANT DX	HCV REAL-TM QUANT DX	HCV GENOTYPE PLUS REAL-TM
INSTRUMENT			
Size of device	SaMag: 100 x 70 x 52 cm SaCycler-96: 210 x 540 x 540 mm		
Weight of device	SaMag: 70kg SaCycler-96: 27kg		
Robustness	Possibility to resume in case of power failure.		
Environmental requirements	SaMag: 30 to 80% RH (non condensing) SaCycler-96: Room temperature (~25°C) max; humidity 50-80%		
Power requirements	AC power; possibility to resume in case of power failure		
Time to battery charge	N/A		
Battery duration (hours)	N/A		
Alternative charging options	N/A		
Ease of use	Keypad and integrated barcode reader for easy set-up.		
Display languages	English		
Built-in memory storage capacity	Yes, and possibility to resume in case of power failure		
Connectivity options	None		
Interpretation of result	Using provided PC software "RealTime_PCR"		
Instrument lifespan	100,000 hours of LED		
Other non-proprietary equipment required	PC with windows operating system (supplied).		
Regulatory approval	CE-IVD		
KIT			
Kit components	Calibrators, high positive control, low positive control, negative control, internal exogenous control		Internal and external (positive and negative).
Kit sizes	1 box		
Internal control(s)	Yes		
Compatible with EQA and which?	The kit was validated using the 2nd WHO International Reference Panel Preparation for HIV-1 Subtypes for NAT (Main), NIBSC code: 12/224.	The kit was validated using the 4th WHO International Standard for HCV for Nucleic Acid Amplification Techniques, NIBSC code: 06/102 15.	
Mean time between failures	Not provided		
Transport and storage	All components of the kit are lyophilized, the kit can be shipped at room temperature and stored at 2-8°C.		Shipped at 2-8°C and stored at -20°C.
Fridge at -80°C required?	No		
Shelf life (of each item in the kit)	12 months		
Performance protocol (steps)	The user just has to add 50µL of extracted viral RNA into the PCR tubes containing lyophilized reagents and transfer the 0.2mL PCR tube to the Real Time PCR instrument (no need to prepare PCR mastermix).		In addition mastermix must be prepared (mix, buffer, taq and MMLV enzymes), as kit is in liquid form.
Non-proprietary components required outside of the kit	Not provided		
Regulatory approval	CE-IVD	CE-IVD	None
In-country approvals	Not provided		
USAGE			
Technical skill required	Medium-highly trained, precision pipetting required at low volumes.		
Applicable settings	Low- to highly-resourced settings.		
Laboratory set-up	Specialised, 1-2 dedicated areas are required.		
Waste disposal requirements	Not provided		

Continued overleaf

Lab-based HIV VL & HCV VL – Sacace Biotechnologies continued

02 | PRICING

HIV VIRAL LOAD							
Instrument		**Reference number**	**FCA ($)**	**Cartridge/reagents**		**Reference number**	**FCA ($)**
SaCycler-96	Real Time PCR instrument, 96-well plate, 5 channels	SC-96I	$20,000	HIV Real-TM Quant Dx	Assay kit	V0-96/3FRT	$20 (without extraction)
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
SaMag	Automatic Nucleic Acid Extractor		$14,000	None			
Cost per device			**$34,000**	**Cost per test result**			**>$20**

HCV VIRAL LOAD							
Instrument		**Reference number**	**FCA ($)**	**Cartridge/reagents**		**Reference number**	**FCA ($)**
SaCycler-96	Real Time PCR instrument, 96-well plate, 5 channels	SC-96I	$20,000	HCV Real-TM Quant Dx	Assay kit	V1-96/3FRT	$20 (without extraction)
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
SaMag	Automatic Nucleic Acid Extractor		$14,000	None			
Cost per device			**$34,000**	**Cost per test result**			**>$20**

03 | TIERED AND VOLUME-BASED PRICING

No information provided.

04 | MAINTENANCE, WARRANTY & TRAINING

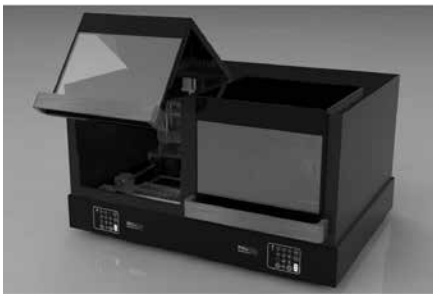
	Description
Training	Provided through local distibutor or directly at Sacace facilities in Como.
Warranty components	1 year on instruments.

05 | CONTACT INFO

Simone Paci
Sacace Biotechnologies -
Product Specialist

Scalabrini street, 22, Como, Italy

Website: www.sacace.com
Tel: + 39 0314892927
Email: specialists@sacace.com



SaMag (automatic NA extraction)

SaCycler - 96
(Real TIme PCR)

LAB-BASED HIV VL, HCV VL & HCV GT
SIEMENS

01 | TECHNICAL AND PERFORMANCE INFORMATION

	HIV VIRAL LOAD	HCV VIRAL LOAD	HCV GENOTYPING
Company	**Siemens**		
Product	**VERSANT HIV-1 RNA 1.5 ASSAY (KPCR)**	**VERSANT HCV RNA 1.0 ASSAY (KPCR)**	**VERSANT HCV GENOTYPE 2.0 ASSAY (LIPA)**
ASSAY			
Intended use (as per regulatory approval)	Quantitation of HIV-1 RNA.	Quantitation of HCV RNA.	Line probe assay that identifies HCV genotypes 1 to 6 and subtypes a and b of genotype 1. Additional subtype information is available in a majority of cases. Intended to be used to guide the selection of treatment type and length for individuals being considered for antiviral treatment who are chronically infected with HCV. Thus intended to be used with samples known to be positive for HCV RNA.
Principle of the assay	Kinetic PCR		Line Probe Assay (LiPA) that utilizes the reverse-hybridization technology.
Target	HIV-1 RNA pol	Highly conserved HCV 5' untranslated region (5' UTR).	5'UTR and core region of the HCV genome.
Genotypes and/ or subtypes	HIV-1: group M (A-H, CRF01_ AE, CRF02_AG), group O	Genotypes 1-6 (1A, 1B, 2A, 2B, 2C, 3A, 4A, 5A, 6A)	Detects genotypes 1-6 and subtypes 1a vs 1b, and subtypes 6 (c-I).
Type of result	Quantitative		Qualitative
Linear range	37 - 11,000,000 copies/mL	15 - 100,000,000 IU/mL (64.5 copies/mL - 430,000,000 copies/mL)	N/A
Output	Viral load		Genotype
DNA or RNA specific?	RNA		
Polyvalency	HBV, CT/GC, CMV, EBV, HSV 1&2, HHV-6, Adenovirus, BKV, VZV, Parvovirus B19, JCV. Open channel enables automation of other third-party assays as well as laboratory developed assays		N/A
PERFORMANCE			
Sensitivity - analytical and clinical (source)	LOD: 37 copies/ml (80IU/ml) as determined following the CLSI MM6-A and CLSI EP17-A guidelines.	Limit of detection: 15 IU/mL (64.5 copies/mL); Analytical Sensitivity was also determined using the 3rd WHO HCV RNA International Standard diluted into pooled human serum or plasma using three reagent lots. The LoD was 7.5 IU/mL for plasma (95% CI: 6.5 - 9.6 IU/mL) and 19.4 IU/mL for serum (95% CI: 16.4 - 24.7 IU/mL).	HCV viral loads as low as 2,106 IU/mL produce reliable genotype results.
Specificity - analytical and clinical (source)	99.7% (n=1055); 95% lower one-sided confidence limit: 99.3%	100% (n = 1,054; 95% lower one-sided confidence limit: 99.7%).	N/A
Bias (source)	Not provided		N/A
Intra-assay precision (source)	Not provided		N/A
Inter-assay precision (source)	Not provided	Total Precision (including lot to lot variation) • 2 log IU/mL: 23.8 - 30.4% (0.11–0.13 log SD) • 3 - 4 log IU/mL: 22.8 - 23.6% (0.10 log SD) • 5 - 8 log IU/mL: 26.5 - 35.6% (0.11 - 0.15 log SD)	N/A
SAMPLE			
Sample preparation (steps)	Fully automated sample extraction using Siemens VERSANT kPCR Sample Prep module and VERSANT Sample Preparation 1.0 Reagents kit.		Manual or fully automated using Siemens VERSANT kPCR Sample Prep module and VERSANT Sample Preparation 1.0 Reagents kit.
Sample type	Plasma	Serum and plasma	
Sample volume	500µL		
Sample stability	Whole EDTA blood: ≤6 hours at room temperature or ≤24 hours at 2-8°C before centrifugation. Plasma: ≤24 hours at room temperature or ≤5 days at 2-8°C.		Store the extracted RNA at 2 - 8°C until processed with the VERSANT Amplification 2.0 Kit (LiPA). If the RNA is not processed immediately within approximately 30 minutes of extraction then store RNA samples at -60° to -80°C.

Continued overleaf

Lab-based HIV VL & HCV VL – Siemens continued

Product	VERSANT HIV-1 RNA 1.0 ASSAY (KPCR)	VERSANT HCV RNA 1.0 ASSAY (KPCR)	VERSANT HCV GENOTYPE 2.0 ASSAY (LIPA)
SAMPLE			
Nucleic acid extraction method	Automated using VERSANT Sample Preparation 1.0 Reagents kit		Manual or automated.
Time to result	≤6 hours for a full plate (96 tests): - Sample preparation system setup: <10 minutes - Sample extraction: <3 hours - Amplification and detection: <3 hours		Variable depending on work flow.
Capacity	96 tests per run: 89 clinical samples, 4 calibrators, 3 controls =178 clinical samples/shift		Autoblot 3000H: 20 samples/run AutoLiPA 48: 48 samples/run
Batching?	Yes, flexible run sizes of 1-96 tests per batch		Yes
Throughput per end-user per hour and/or 8hr day	96 tests per run: 89 clinical samples, 4 calibrators, 3 controls =178 clinical samples/shift		Not provided
INSTRUMENT			
Size of device	VERSANT sample prep module (depth includes autoload tray): W 112.4 x D 100.6 x H 90.5 cm VERSANT amplification/detection module: W 36.8 x D 53.4 x H 45.7 cm		Autoblot 3000H: W 55.9 x H 45.7 x D 19.1 cm AutoLiPA 48: W 80.4 (w) x H 46 x D 45.9 cm
Weight of device	VERSANT Sample prep module: 155kg VERSANT Amplification/detection module: 25kg		Autoblot 3000H: 15.9kg AutoLiPA 48: 47kg
Robustness	Extremely robust		
Environmental requirements	Temperature: 18 - 30°C Humidity: 30 - 80% non-condensing Altitude: 0 - 2,000m Noise: <65 dB (SP module) / <75 dB, 1m distance (AD module)		Autoblot 3000H: • Temperature: 5 - 40°C • Maximum RH: 80% for temperatures ≤31°C decreasing linearly to 50% RH at 40°C • Altitude ≤2,000m AutoLiPA 48: • 15 - 30°C for operation; -10 to 50°C temperature for non-operation • RH of 20 - 90%
Power requirements	100 - 120 V AC at 50 - 60 Hz ± 5% or 200 V - 240 V AC		Autoblot 3000H: • 100 - 240 V, 50 - 60Hz, 3.2 amp max • MAINS supply voltage fluctuations up to ±10% of the nominal voltage • Transient overvoltages typically present on the MAINS supply AutoLiPA 48: 100 - 120 V and 220 - 240 V; 50 - 60 Hz
Time to battery charge	N/A		Not provided
Battery duration (hours)	N/A		Autoblot 3000H: Equipped with a rechargeable lithium battery that has a shelf-life of one year.
Alternative charging options	No		
Ease of use	Communication: 9 pin port; 4 COM ports; 2 network cards for communications between SP and AD modules and for use with a LIS; Windows-based software; LIS-compatible user interface that manages up to 2 separate Analysers (Siemens configuration is not designed for Microsoft Windows domain network environment); Software production complies to ISO 13485; License: Windows XP.		Not provided
Display languages	English		
Built-in memory storage capacity	160 GB hard drive		Not provided
Connectivity options	LIS Interface capability		Not provided
Interpretation of result	Target not detected <37 copies/mL; viral load or >11,000,000 copies/mL	Target not detected <15 IU/mL; viral load or >1 x 10^8 IU/mL	Visual interpretation with interpretation chart or automated with LIPAScan software.
Instrument lifespan	Not provided		Not provided
Other non-proprietary equipment required	Computer and barcode scanner (supplied).		Scanner for LiPAScan software (optional)
Regulatory approval	CE-IVD Directive 98/79/EC		CE-IVD Directive 98/79/EC US FDA-approved (March 2017)

Product	VERSANT HIV-1 RNA 1.0 ASSAY (KPCR)	VERSANT HCV RNA 1.0 ASSAY (KPCR)	VERSANT HCV GENOTYPE 2.0 ASSAY (LIPA)
KIT			
Kit components	VERSANT HIV-1 RNA (kPCR) kit, IVDD Box 1 & 2 and VERSANT Sample Preparation 1.0 Reagents Kit (Box 1 & 2)	VERSANT HCV RNA 1.0 (kPCR) Kit, IVDD Box 1 & 2 and VERSANT Sample Preparation 1.0 Reagents Kit (Box 1 & 2)	HCV Amplification 2.0 Kit (LiPA) HCV Genotype 2.0 Assay (LiPA)
Kit sizes	96 tests/kit		40 tests/kit
Internal control(s)	Yes: internal controls; negative, low positive and high positive controls.		Yes: VERSANT HCV Control 2.0 Kit (LiPA)
Compatible with EQA and which?	Yes		Not provided
Mean time between failures	Not provided		
Transport and storage	Sample prep reagent kit, Box 1: 15-30°C; Box 2: 2-8°C; kPCR Reagent kit, Box 1: -30 to -10°C; kPCR Calibrators and controls kit, Box 2: -90 to -60°C.		HCV Amplification 2.0 Kit (LiPA): -25 to -15°C HCV Genotype 2.0 Assay (LiPA): 2 - 8°C
Fridge at -80°C required?	Yes		No
Shelf life (of each item in the kit)	12 months		
Performance protocol (steps)	(1) Load dedicated sample prep reagents into a trough (2) place reagents on the module, (3) load plasma samples on to sample carrier, (4) place sample carriers on auto load tray of VERSANT sample prep module - from that point on it is fully automated.		Not provided
Non-proprietary components required outside of the kit	Plastics (e.g. tips and plates)		
Regulatory approval	CE-IVD Directive 98/79/EC	CE-IVD Directive 98/79/EC	CE-IVD Directive 98/79/EC US FDA-approved (March 2017)
In-country approvals	Not provided		
USAGE			
Technical skill required	Yes, qualified in molecular practices		
Applicable settings	Highly-resourced settings		
Laboratory set-up	System concept supports either 1- or 2-room technologies		Bench top systems
Waste disposal requirements	Per local regulations and requirements		

02 | PRICING

HIV VIRAL LOAD

Instrument		Reference number	FCA ($)	Cartridge/reagents		Reference number	FCA ($)
kPCR Sample Prep Sub-system	Automated sample preparation	10282928		VERSANT Sample Preparation 1.0 Reagents Box 1	Sample preparation	10286026	$10 - 14
kPCR Amp/Detect Instrument	Amplification and detection	10282939		VERSANT Sample Preparation 1.0 Reagents Box 2	Sample preparation	10286027	
				VERSANT HIV-1 RNA (kPCR) kit, IVDD Box 1	Amplification and detection	10375763	$43 - 58
				VERSANT HIV-1 RNA (kPCR) kit, IVDD Box 2	Amplification and detection	10375764	
				Test panel HIV-1 RNA (KPCR) (RUO)	3 positive controls and 1 negative	10282417	
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
VERSANT KPCR SW V3.1 Install kit and KPCR TDEF software CD V3.2	Installation	10814064 10816436		Disposable tips 1mL Filtered (8 x 480 tips per case)		10282929	
BACK-UPS	Uninterrupted power supply	10638181		Disposable tips 300µL Filtered (12 x 480 tips per case)		10282930	
kPCR SP Workstation	AD PC and mouse, monitor, keyboard, barcode reader	10702391		Sample Prep Reagent Trough kit per 20 sleeves of 6 containers		10489008	
kPCR AD Workstation	AD PC and mouse, monitor, keyboard, barcode reader	10702393		Ultra clear cap strips (120 strips of 8)		10283000	
				96 Deep well plate 2mL (case of 60 plates)		10283255	
				PCR plates barcoded (25)		10282998	
				Waste bag biohazard (200)		10282938	
Cost per device			**$166,000 - 221,600**	**Cost per test result**			**$54 - 72**

Continued overleaf

HCV VIRAL LOAD

Instrument		Reference number	FCA ($)	Cartridge/reagents		Reference number	FCA ($)
kPCR Sample Prep Sub-system	Automated sample preparation	10282928		VERSANT Sample Preparation 1.0 Reagents Box 1	Sample preparation	10286026	$10 - 14
kPCR Amp/Detect Instrument	Amplification and detection	10282939		VERSANT Sample Preparation 1.0 Reagents Box 2	Sample preparation	10286027	
				VERSANT HCV RNA (kPCR) kit, IVDD Box 1	Amplification and detection	10375763	$62 - 86
				VERSANT HCV RNA (kPCR) kit, IVDD Box 2	Amplification and detection	10375764	
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
VERSANT KPCR SW V3.1 Install kit and KPCR TDEF software CD V3.2	Installation	10814064 10816436		Disposable tips 1mL Filtered (8 x 480 tips per case)		10282929	
BACK-UPS	Uninterrupted power supply	10638181		Disposable tips 300µL Filtered (12 x 480 tips per case)		10282930	
kPCR SP Workstation	AD PC and mouse, monitor, keyboard, barcode reader	10702391		Sample Prep Reagent Trough kit per 20 sleeves of 6 containers		10489008	
kPCR AD Workstation	AD PC and mouse, monitor, keyboard, barcode reader	10702393		Ultra clear cap strips (120 strips of 8)		10283000	
				96 Deep well plate 2mL (case of 60 plates)		10283255	
				PCR plates barcoded (25)		10282998	
				Waste bag biohazard (200)		10282938	
Cost per device			**$166,000 - 221,600**	**Cost per test result**			**$72 - 100**

HCV GENOTYPING

Instrument		Reference number	FCA ($)	Cartridge/reagents		Reference number	FCA ($)
AutoLiPA 48 INSTRUMENT	Line probe assay	10313066	$39,375 - 50,000	VERSANT HCV LiPA 2.0 Amplification Kit (IVD) (40 tests)	Amplification	10325050	$1,250 - 2,500
Autoblot 3000H Instrument	Line probe assay	10315618	$17,200 - 20,000	VERSANT HCV LiPA 2.0 Genotype Kit (IVD) (40 tests)	Genotyping	10325052	$3,250 - 10,250
LiPAScan Software (optional)	Software	10291328	$3,125 - 4,375	VERSANT HCV LiPA 2.0 Control Kit (IVD)	Controls	10325051	$812.50 - 1,250
Instrument Accessories		**Reference number**	**FCA ($)**	**Non-proprietary equipment and consumables**		**Reference number**	**FCA ($)**
Auto LiPA 30 Strips Tray		10330923		None			
Auto LiPA 48 Strips Tray		10325628					
AutoBlot 3000 Strips Tray		10315381					
VERSANT LiPA Scan Reading Template		10329226					
Cost per device			**$57,000 - 70,000**	**Cost per test result**			**$132 - 350**

03 | TIERED AND VOLUME-BASED PRICING

No information provided.

04 | MAINTENANCE, WARRANTY & TRAINING

	Description
Leasing or reagent rental (RAP)	Available.
Installation	Complete installation provided by trained Siemens personnel.
Training	Dedicated training on instrument. Electronic training is widely available using Siemens Personalized Education Program (PEP).
Maintenance	Routine preventative maintenance required, and provided by Siemens with service contract.
Length(s) of warranty and additional costs for extended warranty / care plan	One year warranty provided for instrumentation.
Warranty components	Information not provided.
Turnkey option	Information not provided.
In-country / regional technical support availability	Available in all countries where Siemens products are sold.

05 | CONTACT INFO

Alfonso Natale, Ph.D.
Head of Global Sales and Marketing
Molecular Diagnostics, Siemens

725 Potter Street
Berkeley, CA 94710, USA

Website: www.siemens.com/molecular
Tel: +39 335 7780660
Email: alfonso.natale@siemens.com

KPCR

LIPA

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GLOSSARY AND ABBREVIATIONS

INCOTERM GLOSSARY

Incoterms are an internationally recognised collection of terms that specify the responsibility of the buyer and seller in a purchase.[31] The terms used in this report include the following:

EXW (Ex works): Where the seller is responsible for the product, the export packing, and the monitoring and labelling.

FCA (Free carrier): Where the seller is responsible for the product, the export packing, the monitoring and labelling, and the export clearance (including licences, EEI/AES).

CPT (Carriage paid to): Where the seller is responsible for the product, the export packing, the monitoring and labelling, and the export clearance (including licences, EEI/AES), freight forwarder documentation fees, inland freight to main carrier, original terminal charges, vessel loading charges, ocean/air freight, and nominate export forwarder.

CIF (Cost, insurance, and freight): Where the seller is responsible for the product, the export packing, the monitoring and labelling, and the export clearance (including licences, EEI/AES), freight forwarder documentation fees, inland freight to main carrier, original terminal charges, vessel loading charges, ocean/air freight, nominate export forwarder, and marine insurance. In general, companies specify the port to which the product will be delivered.

AIDS: Acquired Immunodeficiency Syndrome.

ART: Antiretroviral therapy

ARV: Antiretrovirals; medicine to treat HIV/AIDS.

Bundled price: When a company sells a package or set of goods or services (in this case tests for different diseases or analytes that are run on the same platform) for a lower price than they would charge if the customer bought them separately.

cAg: Core antigen.

CD4 count: The absolute number of CD4 positive T lymphocytes (T lymphocytes are CD3 positive immune cells) in the blood. CD4 count is measured in cells per microliter (cells/µL) of blood; equivalent to cells per cubic millimetre (cells/mm3). A normal, healthy value for a CD4 count is usually above 500 cells/µL.

CD4 percentage: The percentage of CD4 positive versus CD3 positive lymphocytes in the blood. A normal, healthy value for a CD4% is usually above 29%. Since CD4 counts can vary naturally from day to day, CD4% is a more accurate measurement of the health of the immune system. Children under the age of five years should be tested using CD4% because the number of lymphocytes can be higher in children and therefore using CD4% is more accurate.

CDC: Centers for Disease Control and Prevention in the US.

CE: Conformité Européenne. Europe's regulatory agency for medical drugs and devices.

Clinical: Based on signs, symptoms, morbidities and diseases.

CMV: Cytomegalovirus.

CRF: Circulating Recombinant Form

CT/NG or CT/GC: Chlamydia trachomatis and Neisseria gonorrhoeae.

DBS: Dried blood spot. A spot of blood that is preserved on filter paper through a process of desiccation.

DNA: Deoxyribonucleic acid. The genetic material of living organisms.

DRM: Drug resistance mutation. Genetic mutations of the HIV genome that result in resistance to antiretroviral drugs so that viral replication is no longer suppressed.

EBV: Epstein–Barr virus.

EID: Early infant diagnosis. According to current WHO guidelines, the first diagnostic test should be performed by a virological test when the infant is six weeks of age.

ELISA: Enzyme-linked immunosorbent assay. Also called enzyme immunoassay (EIA).

FDA: Food and Drug Administration. The US FDA is the USA's regulatory agency for medical drugs and devices.

FRET: Fluorescence resonance energy transfer.

FS: Fingerstick, also termed fingerprick. A lancet is used to prick or cut the fingertip to get a drop of capillary blood.

GMP: Good Manufacturing Practice. A production and testing practice that helps to ensure a quality product.

GT: Genotyping.

HBV and HCV: Hepatitis B virus and hepatitis C virus.

HIV: Human Immunodeficiency Virus. There are two types of HIV: HIV-1 and HIV-2. HIV-1 is more widespread and more virulent than HIV-2.

HPV: Human papillomavirus.

Immunologic: Based on the measurement of the immune system (e.g. for HIV the CD4 count or percentage and the change in the CD4 count or percentage over time). Clinico-immunological monitoring is based on both clinical and immunological measurement.

IVD: In vitro diagnostic.

kPCR: Kinetic polymerase chain reaction.

LDC: Least-Developed Countries, according to the United Nations classification.

Continued overleaf

Glossary and Abbreviations continued

LMIC: low-and middle-income countries.

LTR: Long terminal repeat. A conserved region of the HIV genome that is repeated on both ends.

mAb: Monoclonal antibody. A type of mono-specific antibody that binds to only one antigen or epitope.

MRSA: Methicillin-resistant Staphylococcus aureus.

NASBA: Nucleic Acid Sequence Based Amplification.

N/A: Not applicable.

PMTCT: Prevention of mother-to-child transmission. Providing treatment to mothers who are HIV-positive and their infants to prevent vertical infection in utero, intra-partum and post-partum.

POC: Point-of-care.

RAP: Reagent agreement plan. Reagent agreement or reagent rental where products sold (in this case diagnostics or monitoring tests) are increased in price to include an amount to cover the amortized cost of an instrument platform, including maintenance costs, or other equipment. These costs are amortized over the useful life of the instrument system. A RAP requires accurate monthly volume forecasting.

RLS: Resource-limited settings.

RNA: Ribonucleic acid. Similar to DNA but is used to transmit information from DNA (transcription) to proteins (translation).

RT: Reverse transcriptase. An enzyme than transcribes RNA into DNA.

rt-PCR or q-PCR: Real-time or quantitative polymerase chain reaction. A form of PCR that is quantitative.

RUO: Research use only. Usually in connection with the fact that a product has not yet received FDA regulatory approval.

Serologic: Based on the measurement of antibodies in the blood.

SOP: Standard operating procedure.

SVR: Sustained virological response; an undetectable HCV viral load 12 weeks after treatment completion, considered equivalent to a cure.

TB: Tuberculosis. An airbourne disease caused by the pathogen Mycobacterium tuberculosis. MDR- and XDR-TB are multidrug-resistant and extensively drug-resistant TB, respectively.

TBD: To be determined.

TGA: Therapeutic Goods Administration. Australia's regulatory agency for medical drugs and devices.

Total cost of ownership: The fully loaded sum of the direct and indirect costs of a product or system (in this case test result, including reagents, calibrators and controls, equipment, servicing and set-up and logistics).

UNITAID: UNITAID is a global health initiative in great part financed by a solidarity levy on airline tickets. UNITAID uses innovative financing to increase funding for greater access to treatments and diagnostics for HIV/AIDS, malaria and tuberculosis in low-income countries. It is hosted and administered by WHO.

Virologic: Based on the measurement of the virus or a component of the virus (e.g. for HIV, p24 or RNA).

VL: Viral load.

VLT: Viral load test.

WHO: World Health Organization.

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Design/artwork/print:
ACW Ltd
+44 (0)20 8392 4330
www.acw.uk.com

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Médecins Sans Frontières
Rue de Lausanne 78, CP 116
CH-1211 Geneva 21, Switzerland

Tel: + 41 (0) 22 849 84 05
Fax: + 41 (0) 22 849 84 04
Email: access@msf.org

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