

NOVEL POINT-OF-CARE TOOLS FOR
EARLY INFANT DIAGNOSIS OF HIV

JULY 2017



While a decade of investment in conventional laboratory networks has expanded access to Early Infant Diagnosis (EID) testing, only 51% of HIV-exposed infants were tested before two months of age in 2015.¹

The advent of point-of-care (POC) EID technologies² is a breakthrough that creates the opportunity to increase coverage of EID testing. It will allow same-day test results and enable the initiation of earlier treatment, as well as address some of the key limitations of conventional EID networks – in particular long turnaround times for tests and high rates of loss to follow up.

Significant progress has been made in ensuring the quality of new POC EID technologies.

POC EID regulatory approvals and technical evaluations*:

- CE-IVD (Conformité Européenne In Vitro Diagnostics):** Four POC EID technologies have received CE-IVD: Aleré™q HIV-1/2 Detect, Cepheid Xpert®HIV-1 Qual, and Diagnostics for the Real World's SAMBA I HIV-1 Qual Test and SAMBA II HIV-1 Qual Whole Blood Test.
- WHO-PQ (WHO prequalification):** Two POC EID technologies have met WHO requirements: Aleré™q HIV 1/2 Detect³ and Cepheid Xpert®HIV-1 Qual⁴ received WHO prequalification on 13 June 2016.

Independent technical evaluations:

The POC EID Consortium is composed of a group of principal investigators across six countries conducting technical field evaluations of POC EID technologies to expedite the release of independent performance data to accelerate national approval processes and in-country implementation. Results from nine technical field evaluations were consolidated across the six countries. A total of 3,383 specimens were tested using the Aleré™q HIV-1/2 Detect and 4,401 specimens were tested using the Cepheid Xpert®HIV-1 Qual.⁵

Assay	Evaluator	Sample Type	Sensitivity (95% CI)	Specificity (95% CI)
Aleré™q HIV-1/2 Detect	WHO PQ CDC/NHLS	whole blood	98.67% (95.27-99.84)	100.00% (97.59-100.00)
	EID Consortium	whole blood	99.00% (96.45-99.88)	99.97% (99.83-100.00)
Cepheid Xpert® HIV-1 Qual	WHO PQ CDC/NHLS	whole blood	98.86% (93.83-99.97)	100.00% (97.55-100.00)
	EID Consortium	whole blood	96.79% (92.68-98.95)	99.91% (99.76-99.97)
	WHO PQ CDC/NHLS	dried blood spots	99.34% (96.40-100.00)	100.00% (97.60-100.00)

*These approvals are often considered by countries when procuring diagnostic technologies.

WHO RECOMMENDATIONS

The 2016 WHO Consolidated Guidelines on the use of antiretroviral drugs for treating and preventing HIV infection recommend nucleic acid testing (NAT) technologies that are developed and validated for use at or near to the point of care can be used for early infant HIV testing. POC EID provides the opportunity to reduce test turnaround times, limit patient loss along the HIV testing cascade, reduce infant mortality, and allow for task shifting to lower cadres of health workers at decentralized facilities.⁶

CURRENT USE

A number of countries are currently implementing POC EID technologies. Malawi, Mozambique, and South Africa for example, reported results from POC EID pilots in 2016 showing significantly shorter test turnaround times for results and increased patient initiation rates compared to conventional laboratory systems^{7,8,9}. Considering the high and early mortality rate of untreated HIV infected infants^{10,11}, POC EID could also reduce observed infant mortality.



REFERENCES

1. Global Plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive. UNAIDS 2016. <http://www.unaids.org/en/resources/documents/2016/GlobalPlan2016>.
2. UNITAID HIV/AIDS Diagnostics Technology Landscape, 5th edition, October 2015. http://unitaid.org/images/marketdynamics/publications/UNITAID_HIV_Nov_2015_Dx_Landscape.PDF
3. WHO PQ Public Report: Alere™q HIV-1/2 Detect. June 2016. http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/160613PQPublicReport_0226-032-00AlereHIVDetect_v2.pdf?ua=1.
4. WHO PQ Public Report: Cepheid Xpert®HIV-1 Qual. June 2016. http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/160613PQPublicReport_0259-0700-00_XpertQualHIV_v2.pdf?ua=1.
5. S. Carmona et al. Field Performance of Point-of-Care HIV Testing for Early Infant Diagnosis: Pooled Analysis from Six Countries for the EID Consortium. Poster presentation: ASLM2016. December 2016.
6. WHO. (2016) Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection. Geneva, Switzerland.
7. Jani IV, Meggi B, Mabunda N, Vubil A, Tobaiwa O, Bollinger T, Mudenyanaga C, Loquiha O, Vojnov L, Peter T. (2016). Effect of point-of-care early infant diagnosis on retention of patients and rates of antiretroviral therapy initiation on primary health care clinics: a cluster-randomized trial in Mozambique. Presented at the International AIDS Society: AIDS2016, Durban, South Africa.
8. Mwenda R. (2016). Impact of Point-of-Care EID Testing into the National EID Program: Pilot Experiences from Malawi. Presented at the International AIDS Society: AIDS2016, Durban, South Africa.
9. Technau K, Sherman G, Bhowan K, Murnane P, Coovadia AH, Kuhn L. Comparing Point of Care to Laboratory HIV PCR testing at birth in a hospital setting in Johannesburg, South Africa. Presented at the 8th International Workshop on HIV Pediatrics, Abstract 0_14, Durban, South Africa.
10. Bourne DE, Thompson M, Brody LL, Cotton M, Draper B, Laubscher R, Fareed Abdullah M, Myers JE. Emergence of a peak in early infant mortality due to HIV/AIDS in South Africa. AIDS 2009; 23:101-106.
11. Newell ML, Coovadia H, Cortina-Borja M, Rollins N, Gaillard P, Dabis F. Ghent IAS working group. Mortality of infected and uninfected infants born to HIV-infected mothers in Africa: a pooled analysis. Lancet 2004; 364:1236-1243.

SUMMARY OF RECOMMENDATIONS

CONCLUSIONS

Sufficient evidence has been generated on the performance of these assays in the intended field settings to support rapid national regulatory approval and initiation of scale-up. Performance was consistent between laboratory and field settings, and across countries. Further technical evaluations of these technologies are unlikely to add value, but may

instead delay implementation and timely diagnoses of HIV-infected infants, a critical and vulnerable population.

National regulatory agencies are encouraged to not delay adoption by conducting further evaluations, but instead adopt a rapid and streamlined registration and national approval process for immediate implementation.

Based on the CE-IVD and WHO PQ approvals, robust results from independent technical field evaluations, procurement eligibility, the WHO recommendation for the use of POC EID, and initial patient impact results from implementation pilots, countries should begin planning the implementation of POC EID by incorporating POC EID into National HIV Care and Treatment Guidelines, National Strategic Plans, PEPFAR Country Operational Plans, Global Fund grant applications, and HIV Program budgets.

For more information, contact:

World Health Organization
Department of HIV/AIDS
20, avenue Appia
1211 Geneva 27
Switzerland

E-mail: hiv-aids@who.int
www.who.int/hiv
WHO/HIV/2017.16
© World Health Organization 2017
Some rights reserved.
Licence: CC BY-NC-SA 3.0 IGO



INFORMATION NOTE

HIV DIAGNOSTICS