Diagnostics – Technical Frequently Asked Questions

Are different types of tests supplied through the Consortium interchangeable?

The test kits currently supplied through the Consortium (molecular or nucleic acid assays) are not interchangeable, even though they are based on the same principles and methodology. The test kits provided through the Consortium can be divided into two main groups depending on the way they are used: Automated and Manual.

The Automated test kits are tests considered to require limited or very little hands-on skills and time by the technician. Furthermore, these tests typically run on closed systems, meaning they can only be run on the specific platform. For example, some Automated tests currently being procured by the Consortium, include Abbott Realtime SARS-CoV-2 tests for use on the Abbott m2000 system, Xpert Xpress SARS-CoV-2 for use on the Cepheid GeneXpert system, and cobas SARS-CoV-2 Qualitative assay for use on the Roche cobas 6800/8800 systems. The Thermo Fisher TaqPath COVID-19 kit can also be considered semi-automated if using the King Fisher automated extraction system prior to amplification.

The manual test kits require more manual steps and therefore hands-on time by the technician performing the test procedure, particularly for the nucleic acid extraction process. Manual test kits are generally run on open systems (platforms) meaning they can be run on a variety of different PCR machines (if validated by the manufacturer in the Instructions for Use) and may or may not require an extraction kit to be procured separately. Manual test kits currently being procured by the Consortium include the BGI Real-time fluorescent RT-PCR kit for detecting 2019-nCoV and the Thermo Fisher TaqPath COVID-19 Kit.

Additional automated and manual test kits may be procured in the future by the Consortium. Furthermore, additional tests, such as antigen- and antibody-based tests may also be procured by the Consortium as and when guidance and availability are clearer.

Are the two Thermo Fisher test kits procured by the Consortium the same or different?

Yes, the 'automated' and 'manual' Thermo Fisher test kits are the same – TaqPatth COVID-19 Combo kit. The extraction component of the Thermo Fisher test kit, **Viral RNA Extraction:** MagMAX Viral Pathogen Nucleic Acid Isolation Kit, can be used either manually or automated depending on the equipment available in the laboratory. The King Fisher automated extraction system allows for the Thermo Fisher extraction kit to be used in an automated way. Without this device, the test kit requires manual nucleic acid extraction using a magnetic stand.

Are sample collection kits (swabs and viral transport media) included in the test kit?

The sample collection kits are generally not included in the test kit. For the BGI test kit bundle, however, sample collection kits are included. Sample collection kits are available in the Supply Chain catalogue.

How do I select the items available in the Supply Chain catalogue?

COVID-19 molecular (also called nucleic acid) testing requires three defined stages: 1) Sample collection and transport; 2) Viral RNA extraction; and 3) Viral RNA detection. This document found here provides guidance on how to order specific tests through the COVID-19 Supply Portal.

Can I still request the TIB Molbiol test through the Supply Chain catalogue?

Yes, the SarbecoV E-gene EAV test kit manufactured by TIB Molbiol can still be requested and procured through the Supply Chain catalogue. This can be done in the same way as previously.

Are any specific equipment necessary to use the available test kits procured through the Consortium?

Yes, specific pieces of equipment are necessary to conduct COVID-19 testing, depending on the test kit.

The automated tests currently procured through the consortium are used on 'closed systems', meaning that the test reagents are proprietary and can only be run on the specific platform:

- Abbott Real-time SARS-CoV-2 test: for use on the Abbott m2000 system
- Cepheid Xpert Xpress SARS-CoV-2 test: for used on the GeneXpert system
- Roche cobas SARS-CoV-2 Qualitative assay: for use on the Roche cobas 6800/8800 system

Of note, the Thermo Fisher TaqPath COVID-19 test kit can also be considered to be semi-automated if used with the King Fisher automated extraction system.

The manual test kits currently procured through the consortium (BGI and Thermo Fisher) require a table top centrifuge (speed not lower than 10,000 rpm), vortex, a metal heater or water bath, refrigerator, and -20°C freezer.

Note: The Viral RNA extraction kits provided by BGI and Thermo Fisher are magnetic-based and therefore require magnetic stands for tubes and plates. These can be re-used in the laboratory. Considering this and in order to ensure the use of the kits, magnetic stands are included within initial shipments. Additional magnetic stands can be provided.

For the manual tests currently procured through the consortium (BGI and Thermo Fisher), the **RT-PCR reaction** process requires a table top centrifuge (with rotor for microplates), vortex and freezer.

The thermocycler for performing the BGI and Thermo Fisher test kits must be able to detect the following dyes:

RT-PCR kit for detecting 2019-nCoV Kit by BGI		
Reported dye	**Detector**	**Wavelength**
FAM	RNA of 2019-nCoV	517 nm
VIC	Control	551 nm

TaqPath COVID-19 CE-IVD RTPCR kit by Thermo Fisher		
Reported dye	**Detector**	**Wavelength**
FAM	ORF 1ab	517 nm
VIC	N gene	551 nm
ABY	S Gene	580 nm
JUN	MS2 (Control)	617 nm

Note: In order to read the dyes, the thermocycler machine might need a software update and/or calibration.

The currently procured manual tests have been validated using the following RT-PCR machines	
BGI: ***RT-PCR kit for detecting 2019-nCoV Kit***	LightCycler 480, ABI 7500 and SLAN96

Thermo Fisher: ***TaqPath COVID-19 CE-IVD RT-PCR kit***	Applied Biosystems 7500, 7500 Fast & 7500 Fast Dx Real-Time PCR Systems, QuantStudio 5 (96-well, 0.1 mL and 0.2mL), 5Dx and 7 Flex (384 well)

What are the consumables and additional reagents needed to use the test kits? Is there a way to calculate their quantities?

Several of the currently available test kits through the Consortium come as a bundled product. All contain both the extraction and PCR kits, some include sample collection kits while others may include the necessary consumables (pipette tips, centrifuge tubes, or plates). The BGI test kit bundle also contains the sample collection kits. Sample collection kits for other tests can be requested through the Supply Chain portal.

A reagent calculator has been developed to support countries and laboratories to ensure procurement of all necessary, non-proprietary consumables and reagents for each test kits. Please find the reagent calculator on the WHO Operations website.

What are the transportation and storage requirements for each test?

Product	Storage
Abbott Realtime SARS-CoV-2 (**Abbott Molecular Inc**)	–15°C to –25°C
RT-PCR kit for detecting 2019-nCoV Kit (**BGI**)	–18°C or lower
Xpert® Xpress SARS-CoV-2 (**Cepheid AB**)	2°C to 28°C
cobas SARS-CoV-2 Qualitative assay (**Roche Molecular Systems, Inc**)	2°C to 8°C
TaqPath Covid-19 Combo Kit (**Thermo Fisher**)	–10°C to –30°C

Some control components may require different storage conditions. These individual components' storage requirements should reviewed as well as the expiration dates on arrival for appropriate storage.

What is the shelf life of the tests?

The self-life of the currently procured tests through the Consortium are (these are likely to be updated with additional product testing and time, please refer to ongoing real-time stability studies):

- Abbott Realtime SARS-CoV-2: 18 months
- RT-PCR kit for detecting 2019-nCoV Kit (BGI): 6 months at –18°C or lower
- Xpert Xpress SARS-CoV-2 (Cepheid): 6 months
- Cobas SARS-CoV-2 Qualitative assay (Roche): 12 months
- TaqPath Covid-19 Combo Kit (Thermo Fisher): 12 months

Where can I find more information on each of the test kits, for example the Instructions for Use?

All the relevant information concerning test kits with WHO emergency use listing (EUL), including the Instructions for Use and WHO EUL Public Reports, are available on WHO's COVID-19 emergency use listing page:
https://www.who.int/diagnostics_laboratory/EUL/en/

In particular, of the products currently procured through the Consortium, Instructions for Use can be found here:
https://www.who.int/diagnostics_laboratory/eual/listing/en/

Are there other test kits that can be considered but yet aren't currently procured through the Consortium?

Additional automated and manual tests may be procured in the future by the Consortium. Furthermore, additional tests, such as antigen- and antibody-based tests may also be procured by the Consortium as and when guidance and availability are clearer. However, if additional testing capacity is needed, the following sites can be reviewed to make an informed decision regarding additional tests that can be considered for procurement:

- WHO prequalification Emergency Use Listing (EUL): (https://www.who.int/diagnostics_laboratory/EUL/en/). The IVDs on this list have been expeditiously assessed by the WHO's prequalification team to assist interested procurement agencies and Member States on the suitability for use of a specific IVD, based on a minimum set of available quality, safety, and performance data.
- WHO Advice to end-users of IVDs for COVID-19 testing: (https://www.who.int/diagnostics_laboratory/procurement/200422_who_info_covid_falsified_ivds_en.pdf). This document gives special advice on falsified in vitro diagnostics for SARS-CoV2.
- If you have a problem with any product for COVID-19 testing, please fill in a IVD complaint handling form and send to the manufacturer and to WHO at rapidalert@who.int https://www.who.int/diagnostics_laboratory/postmarket/150804_pms_guidance_annex3.docx
- Foundation for Innovative New Diagnostics (FIND) webpage: (https://www.finddx.org/covid-19/). This site contains a list of tests kits that have been evaluated in various laboratories as well as independent performance data.