Ordering COVID-19 Diagnostics (SARS-CoV-2 Polymerase Chain Reaction) through the Global Fund: Frequently Asked Questions
21 September 2020

WHO CONSORTIUM AND ALLOCATION MODEL

1. **How is the Global Fund ensuring access to SARS-CoV-2 diagnostics for countries?**

   The Global Fund is continuing to work closely with key partners, international organizations, governments and technical agencies through the [Diagnostics Consortium](#) to rapidly and equitably support access to COVID-19 diagnostics for low- and middle-income countries.

   From September 2020, the Global Fund, the Global Drug Facility (GDF), the Pan-American Health Organization (PAHO), UNICEF, and the United Nations Development Programme (UNDP) are the major procurers for SARS-CoV-2 Polymerase Chain Reaction (PCR) tests and have secured production capacity with major manufacturers to operationalize the WHO allocation model and ensure equitable access to the available supplies. The WHO allocation model represents the current total volumes available from these manufacturers to all WHO Consortium-eligible countries, regardless of funding source for the period from September 2020 to February 2021. The Diagnostics Consortium has secured production capacity to cover the volumes in the WHO allocation model. The Global Fund can also support the purchase of manual PCR tests for all implementer countries.

   The Global Fund website has information about our COVID-19 [Response Mechanism](#), other [grant flexibilities](#), [health product supply](#) and [quality assurance requirements](#) to support implementing countries.

2. **How are SARS-CoV-2 diagnostic volumes allocated to countries? Will countries with small orders have similar access as larger purchasers?**

   [WHO’s allocation model](#) for products will continue to cover 140+ countries. The allocation is based on the WHO Country Office and for Africa Centres for Disease Control and Prevention current diagnostic instrument mapping. It considers each country’s population, health system vulnerability, testing capacity and COVID-19 epidemiological situation. WHO has allocated initial volumes to countries based on expected product availability.

   Today, there is still significant global demand for these products and supply is limited. Given the challenges in securing these diagnostic products, the Global Fund will follow the WHO allocation model for all its supported countries and allow the use of grant funds, including C19RM funds, and non-grant funding for the purchase of diagnostic products.
3. **What diagnostic products has the WHO Consortium allocated to countries?**

WHO’s Diagnostics Consortium Initial Allocation for Cepheid GeneXpert SARS-CoV-2 Tests list for the September 2020 to February 2021 period allocated volumes of 1 million tests. Another million is expected to be announced in early October 2020, for the same period, which will bring the total Cepheid allocation to 2 million tests over the next 6 months.

4. **How does my country find out its WHO allocation for COVID-19 diagnostics?**

Principal Recipients should reach out to their Global Fund Country Team contacts or WHO Country Office contacts to receive notifications of their allocated quantities.

When reaching out to WHO, Principal Recipients should contact the WHO Country Office Finance Officer or alternatively, the Incident Manager / Technical Officer if Finance Officer is unavailable.

5. **My country’s diagnostic needs exceed the volumes allocated by WHO. How can I express additional quantities required above the WHO allocation?**

Countries should express their full demand in their Global Fund C19RM funding request and through the WHO Supply Portal.

6. **Can my country purchase additional volumes of the diagnostic tests for SARS-CoV-2 included in the WHO allocation using other sources of funding?**

No. The total number of tests allocated to a country covers all sources of funding to deliver on the intent of WHO allocation to ensure equitable access to low- and middle-income countries.¹

7. **What options exist if my country is not allocated enough Cepheid cartridges?**

Given the current supply situation for COVID-19 diagnostics, with molecular diagnostics supplies being constrained relative to demand, a country’s allocated volumes are likely to be lower than demand. Countries should consider including other molecular diagnostic tests from suppliers such as Abbott or Roche, or manual diagnostic tests in their testing plans.

Per WHO guidance on antigen rapid tests (published 11th September 2020), countries may also consider developing a national testing strategy that include antigen rapid diagnostic tests (Ag-RDT) and molecular -i.e. PCR tests.

Overall, available volumes are likely to be lower than demand, and the Global Fund will work closely with manufacturers to quickly allocate any additional volumes that become available (e.g. due to production ramp up) at a transaction level, in line with a country’s registered demand as submitted to the WHO Supply Portal and as articulated in their Global Fund C19RM funding request.

8. **My country ordered Abbott or Cepheid tests well before the WHO allocation model was developed. Will these orders affect my country’s allocation?**

Yes. The WHO allocation model for September 2020 to February 2021 considers any test volumes procured above equitable allocation, either directly with manufacturers or with organizations, to ensure there is equitable distribution of tests to countries.

---

¹ As of September 2020, domestic or other funds can be used to access allocated products from Consortium suppliers through the channels of the main procurers (Global Fund, GDF, PAHO, UNDP, UNICEF).
9. Can my country procure other, non-WHO Consortium allocated SARS-CoV-2 diagnostic tests using Global Fund funding?

Yes. However, when purchasing with Global Fund funding, countries must procure quality assured COVID-19 diagnostics products, which comply with the Global Fund Quality Assurance Policy for Diagnostics Products and the quality assurance requirements as approved by the Global Fund’s Board. Accordingly, the Global Fund maintains a list of eligible SARS-CoV-2 diagnostic test kits and equipment (List of SARS-CoV-2 Diagnostic Test Kits and Equipment Eligible for Procurement: COVID-19) which will be updated regularly.

10. Will other SARS-CoV-2 diagnostic tests be available to procure through wambo.org?

Today, Abbott, Cepheid, Hologic, Roche and Thermo Fisher SARS-CoV-2 diagnostic tests are available in wambo.org.

Over time, the Global Fund is contracting with additional manufacturers of COVID-19 diagnostic tests that can be purchased with Global Fund funds and make these products available in wambo.org.

ABBOTT AND CEPHEID SAR-CoV-2 DIAGNOSTIC TESTS

11. Can my country use the existing GeneXpert instrument for COVID-19 testing?

Yes. To run the test, the instrument will need GeneXpert Dx software version 4.7b or higher. GeneXpert Infinity-80 and Infinity-48s systems will need software version 6.4 or higher. The majority of instruments will already have this software installed.

Countries must ensure there is enough remaining capacity on the same instrument to ensure continuity of diagnostics for HIV EID and TB.

12. Are the Consortium-agreed prices for Cepheid and Abbott all-inclusive of materials needed to run the tests?

The prices for Abbott and Cepheid are inclusive of the test and materials required to run the test, including reagents, consumables and controls, but do not comprise the materials required for sample collection or other items, as detailed in the table below:

<table>
<thead>
<tr>
<th></th>
<th>Abbott Realtime SARS-COV-2 Amplification Reagent Kit</th>
<th>Cepheid Xpert Xpress SARS-COV-2 kit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Price includes:</strong></td>
<td>The test and materials needed to run the test:</td>
<td>The test and materials needed to run the test:</td>
</tr>
<tr>
<td></td>
<td>Reagent kit; control kit; 1ml disposable tips;</td>
<td>Xpert Xpress kit; cartridges with integrated reaction tubes;</td>
</tr>
<tr>
<td></td>
<td>0.2 ml disposable tips; MasterMix tubes; deep</td>
<td>disposable transfer pipettes; and CD (assay definition file and instructions).</td>
</tr>
<tr>
<td></td>
<td>well plates; reaction vessels; reagent vessels;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>waste bags; optical reaction plate; optical</td>
<td></td>
</tr>
<tr>
<td></td>
<td>adhesive covers; and mSample preparation system DNA.</td>
<td></td>
</tr>
<tr>
<td><strong>Materials required for sample collection not included:</strong></td>
<td>Nylon swab; viral transport media tube; and ethanol required for TNA extraction.</td>
<td>Nasopharyngeal swab collection kit</td>
</tr>
<tr>
<td><strong>Other items not included:</strong></td>
<td>Machines and related warranties, training, installation and calibration</td>
<td></td>
</tr>
</tbody>
</table>
13. **Do I need a Biosafety Cabinet Class-II for COVID-19 testing using the Cepheid GeneXpert platforms?**

As per the latest [WHO Biosafety guidelines](https://www.who.int/publications/i/item/laboratory-biosafety-guidance-related-to-coronavirus-disease-(covid-19)) for COVID-19 diagnostic testing, Biosafety level 2 (BSL-2) is still recommended for nucleic acid amplification tests. However, Point of Care (POC) or near-POC assay (e.g., GeneXpert testing) can be performed on a bench without using a Biosafety cabinet with proper biosafety procedures in place. In addition, each institution is required to conduct a local risk assessment to ensure competency to safely perform testing with risk control measures in place and ensure availability of and appropriate use of personal protective equipment by laboratory staff.

14. **Do Abbott and Cepheid SARS-CoV-2 diagnostic test items need special storage conditions during transportation?**

Yes. COVID-19 diagnostic tests from Abbott and Cepheid require special transportation and storage conditions. The tests' documentation will state the necessary storage conditions, for example, Cepheid products require cool temperatures and Abbott test kits include frozen items.

**ORDERING SARS-CoV-2 DIAGNOSTIC TESTS**

15. **How do I purchase SARS-CoV-2 diagnostic tests from Consortium suppliers?**

Initially from September 2020 onwards, countries with a Global Fund grant and approved funding for SARS-CoV-2 diagnostic procurement may purchase diagnostic tests using an accelerated order process through the Global Fund’s Supply Operations Department.

Principal Recipients with approved funding should submit a request for procurement of these tests through wambo.org or, if not registered to wambo.org, may contact their Global Fund Country Teams to start the order process.

16. **Can I procure SARS-CoV-2 diagnostic tests from Consortium suppliers without a Global Fund grant?**

Principal Recipients with approved funding should submit a request for procurement of these tests through wambo.org or, if not registered to wambo.org, may contact their Country Teams to start the order process.

Governments in Global Fund-eligible and transitioned countries can also procure tests using non-Global Fund sources of funding through wambo.org or through the other procurement partners of the Diagnostics Consortium (GDF, PAHO, UNICEF, UNDP) may be used. If interested in using wambo.org, contact the Global Fund Supply Operations Department or the Country Team for more information.

17. **I am a Principal Recipient that has never used the wambo.org platform before. How much time will it take me to get access to the platform and become familiar with using it?**

A rapid process has been developed for Principal Recipients that have never used the wambo.org platform to purchase orders of automated COVID-19 diagnostic tests. No onboarding process will be required. Order details will be confirmed via e-mail through an Order Form, including legal conditions which will have to be signed by an authorized signatory of the Principal Recipient. The
Purchase Order will be issued through the wambo.org platform on behalf of the Principal Recipient after offline (e-mail) confirmation. Principal Recipients are encouraged to respond to all requests for confirmations in a timely manner to meet the target of issuing the PO in three days.

18. My country has lengthy importation procedures. How will these be managed if orders are processed quickly?

Depending on the available supplies, the timeline from initial request to in-country delivery can take as little as two weeks. Given the special storage and transportation conditions required for these products, we will only be able to process orders and allocate volumes if importation procedures are confirmed to be accelerated to accommodate rapid deliveries.

19. When can I expect to receive the quantity of tests in my allocation?

If you have approved funding, the requisition for COVID-19 diagnostic tests can be initiated, and the order confirmed with the manufacturer. We are closely monitoring the supply situation and strive to plan according to your delivery preferences. However, there are limited available volumes which vary on a weekly basis. To optimize deliveries, we may need to either bring forward or push back a delivery depending on the available volumes and approved orders waiting to be served. To support this process, we ask that Principal Recipients respond urgently to any inquiries from the Global Fund or Procurement Service Agents.

20. What if my country is not eligible for Global Fund funding?

Buyers in Global Fund non-eligible countries can channel orders to the Stop TB Partnership’s Global Drug Facility, PAHO’s Strategic Fund, UNICEF or UNDP.