

# Ordering COVID-19 Diagnostics through the Global Fund: Frequently Asked Questions

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## SARS-CoV-2 Antigen-Detecting Rapid Diagnostic Tests

### 1. Will SARS-CoV-2 Antigen-Detecting Rapid Diagnostic (Ag RDTs) be available for financing through Global Fund COVID-19 grant flexibilities and C19RM?

The Global Fund will make SARS-CoV-2 Ag RDTs available for procurement to countries through its funding mechanisms when:

- i. Countries have endorsed the use of these tests in their national COVID-19 testing strategies.
- ii. They are planned to be used as recommended in the [WHO guidance](#).
- iii. SARS-CoV-2 Ag RDTs meet the quality assurance requirements as per the current Global Fund quality assurance policy supplemented by the [Interim Quality Assurance Requirements for the Procurement of COVID-19 Diagnostic Products](#).

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. Is there a list of eligible SARS-CoV-2 Ag RDTs?

The list of Ag RDTs for COVID-19 testing eligible for Global Fund support is included in the [List of SARS-CoV-2 Diagnostic Test Kits and Equipment Eligible for Procurement: COVID-19](#). Currently the SD Biosensor “Standard Q COVID-19 Ag test” and Abbott “Panbio COVID-19 Ag Rapid Test Device” are eligible for procurement and commercially available to LMICs via the Global Fund’s Pooled Procurement Mechanism.

**3. Will SARS-CoV-2 Ag RDTs tests replace standard SARS-CoV-2 Polymerase Chain Reaction (PCR) tests?**

The Global Fund is making both types of products accessible to countries. The Ag RDTs are currently recommended for specific target populations and contexts. The Ag RDTs are not intended to replace PCR. Further guidance on this matter is expected from WHO soon.

**4. Will there be an allocation of SARS-CoV-2 Ag RDT tests? Meaning, a set amount of tests assigned to countries?**

No. There is currently no allocation of Ag RDTs for countries. It is envisaged that sufficient supply is available to meet demand with the current available funding.

**5. How can my country procure SARS-CoV-2 Ag RDTs using Global Fund funding? How does my country place orders for Ag RDTs?**

The Global Fund is making SARS-CoV-2 Ag RDTs available through the Global Fund's Pooled Procurement Mechanism (PPM). Principal Recipients currently procuring through PPM can login to browse and submit requisitions for all available SARS-CoV-2 Ag RDTs products using the normal process (search SD BIOSENSOR~13108 and select Standard Q COVID-19 Ag test Or search Abbott and select Panbio COVID-19 Ag Rapid Test Device).

Principal Recipients not currently participating in the Global Fund's Pooled Procurement Mechanism should reach out to [onboarding@Wambo.org](mailto:onboarding@Wambo.org), copying their Country Team. We have dedicated resources to expedite this process given the urgency of the supply situation.

**6. Can my country procure SARS-CoV-2 Ag RDTs through wambo.org using other sources of funding?**

Governments and non-governmental organizations in Global Fund-eligible and transitioned countries can also procure SARS-CoV-2 Ag RDTs tests using non-Global Fund sources of funding. This can be done through wambo.org or other procurement channels. If interested in using wambo.org, please follow the process described above.

**7. What are the prices for SARS-CoV-2 Ag RDTs? Are the prices all-inclusive of materials needed to run the tests?**

The product price for SD Biosensor tests is ~US\$ 124.25 per pack (25 tests) while the product price for Abbott Panbio COVID-19 Ag Rapid Test Device is ~US\$ 125 per pack (25 tests). For both products, the price is all-inclusive, and each pack comes with test devices individually pouched with desiccant, extraction buffer tubes, nozzle caps, sterile swabs and instructions for use. The costs of freight insurance and procurement agent's fees need to be added to this price.

As other products become eligible for procurement, we will update this FAQ to include the prices of other tests. Information on prices for other eligible Ag-RDTs for COVID testing will also be included in the Global Fund Website for [diagnostics procurement](#)

**8. Where can my country find more details on the use, specification and performance for SARS-CoV-2 Ag RDTs, including storage conditions?**

The following WHO resources provide the details on the use, specification and performance for necessary storage conditions:

- [Instructions for use for the Standard Q COVID-19 Ag test](#)
- [Instructions for use for Panbio COVID-19 Ag Rapid Test Device](#)

## **9. What is the expected lead time for SARS-CoV-2 Ag RDTs?**

Requisitions for SARS-CoV-2 Ag RDTs can be processed quickly and RDTs are expected to be readily available from the manufacturers within a few weeks. The overall lead time to the country will depend on availability of freight routes and how quickly importation approval and waivers are organized by Principal Recipients. Lead times are therefore expected to be range between 1-3 months depending on the freight and approvals.

To optimize lead time, we ask that Principal Recipients respond urgently to any inquiries from the Global Fund or Procurement Service Agents and also facilitate the importation approval.

## **10. Can we procure antibody tests using Global Fund resources?**

No. Antibody-based detection RDT for COVID-19 testing are still not recommended by the WHO for diagnosis of acute infection and clinical management. The Global Fund is currently not envisaging procuring antibody tests.

## **SARS-CoV-2 Polymerase Chain Reaction Tests**

### **11. How is the Global Fund ensuring access to SARS-CoV-2 PCR 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, the United Nations Development Programme (UNDP), and the WHO 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 website has information about our COVID-19 [Response Mechanism](#), other [grant flexibilities](#), [health product supply](#) and [quality assurance requirements](#) to support implementing countries.

### **12. 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 of some of them 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.

**13. What diagnostic products has the WHO Consortium allocated to countries?**

The Diagnostics Consortium has initially allocated 1 million Cepheid GeneXpert SARS-CoV-2 Tests for the September 2020 to February 2021 period. Another one million is expected to be announced in October 2020, for the same period, which will bring the total Cepheid allocation to 2 million tests over the six months period.

An indicative allocation for Abbott and Roche SARS-CoV-2 diagnostic tests is also available from the WHO Country Office and the Global Fund Supply Operations Department.

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

WHO has communicated the total volumes available through their country offices and are contained in the list: [Diagnostics Consortium Initial Allocation for Cepheid GeneXpert COVID-19 Polymerase Chain Reaction Tests](#).

For information on Abbott and Roche SARS-CoV-2 diagnostic tests initial volumes please contact the WHO Country Office and the Global Fund Supply Operations Department.

**15. 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](#).

**16. 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.<sup>1</sup>

**17. What options exist if my country is not allocated enough Cepheid tests?**

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, Hologic, Roche or Thermo Fisher, or manual diagnostic tests in their testing plans.

Per [WHO guidance on antigen rapid tests](#) (published 11 September 2020), countries may also consider developing a national testing strategy that include antigen rapid diagnostic tests (Ag-RDT).

**18. My country ordered 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.

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<sup>1</sup> As of September 2020, domestic or non-Global Fund finances can be used to access allocated products from Consortium suppliers through the channels of the main procurers (Global Fund, GDF, PAHO, UNDP, UNICEF, and WHO).

**19. Will Abbott, Hologic, Roche and Thermo Fisher SARS-CoV-2 diagnostic tests be available for procurement?**

Volumes of Abbott, Hologic and Roche Cobas 6800/8800 SARS-CoV-2 diagnostic tests are also available for procurement through [wambo.org](http://wambo.org) and other procurement channels. Please check the placing orders section to know how to procure these tests.

**20. To which countries can Abbott SARS-CoV-2 diagnostic tests be made available?**

Access to Abbott SARS-CoV-2 diagnostic tests has been expanded beyond Sub-Saharan African countries to 5 Asian countries (Cambodia, Malaysia, Myanmar, Thailand and Vietnam) and 8 countries in Latin America (Bolivia, Ecuador, El Salvador, Haiti, Panama, Peru, Paraguay and Trinidad & Tobago). If there is interest from other countries to use Abbott tests, please contact [onboarding@Wambo.org](mailto:onboarding@Wambo.org).

**21. Which countries can be supplied with Roche SARS-CoV-2 diagnostic tests?**

Cote d'Ivoire, Eswatini, Mozambique, Nigeria, Rwanda, Tanzania, Uganda and Zambia can have access to Roche SARS-CoV-2 diagnostic tests. If there is interest from other countries to use Roche tests, please contact [onboarding@Wambo.org](mailto:onboarding@Wambo.org). This test requires the Roche Cobas 6800 or 8800 platform.

**22. Can I procure Abbott and Roche Cobas 6800/8800 diagnostic tests through [wambo.org](http://wambo.org) without a Global Fund grant?**

Yes. Governments in Global Fund-eligible and transitioned countries can also procure tests using non-Global Fund sources of funding through [wambo.org](http://wambo.org), as described [here](#).

**23. Can my country procure other, SARS-CoV-2 diagnostic tests using Global Fund financing?**

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. Regardless of whether procuring Global Fund financing or other sources of financing, only tests that comply with Global Fund Quality Assurance policy will be listed and available for procurement through [wambo.org](http://wambo.org).

**24. 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:

	Abbott Realtime SARS-COV-2 Amplification Reagent Kit	Cepheid Xpert Xpress SARS-COV-2 kit
<b>Price includes:</b>	<b>The test and materials needed to run the test:</b> Reagent kit; control kit; 1ml disposable tips; 0.2 ml disposable tips; MasterMix tubes; deep well plates; reaction vessels; reagent vessels; waste bags; optical reaction plate; optical adhesive covers; and mSample preparation system DNA.	<b>The test and materials needed to run the test:</b> Xpert Xpress kit; cartridges with integrated reaction tubes; disposable transfer pipettes; and CD (assay definition file and instructions).
Materials required for sample collection <b>not included:</b>	Nylon swab; viral transport media tube; and ethanol required for TNA extraction.	Nasopharyngeal swab collection kit
<b>Other items not included:</b>	Machines and related warranties, training, installation and calibration	

**Placing Orders for SARS-CoV-2 Diagnostic Tests**

**25. How do I purchase SARS-CoV-2 diagnostic tests using Global Fund grant funds?**

Principal Recipients with approved funding should submit a request for procurement of these tests through wambo.org. If not registered to wambo.org, Principal Recipients can contact [onboarding@wambo.org](mailto:onboarding@wambo.org) and their Country Team.

**26. Can I procure SARS-CoV-2 diagnostic tests with non-Global Fund finances?**

Yes. Governments in Global Fund-eligible and transitioned countries can also procure tests using non-Global Fund sources of funding through wambo.org, if not registered to wambo.org please follow the process described above.

Governments can also procure tests using non-Global Fund sources of funding through the other procurement partners of the Diagnostics Consortium (GDF, PAHO, UNICEF, UNDP, WHO).

**27. 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 require signature from 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 an 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.

**28. 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.

**29. 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. 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.

**30. 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.

**31. 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<sup>2</sup> 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.<sup>3</sup> 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.

**32. 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.

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<sup>2</sup> [https://www.who.int/publications/i/item/laboratory-biosafety-guidance-related-to-coronavirus-disease-\(covid-19\)](https://www.who.int/publications/i/item/laboratory-biosafety-guidance-related-to-coronavirus-disease-(covid-19))

<sup>3</sup> [https://www.who.int/publications/i/item/laboratory-biosafety-guidance-related-to-coronavirus-disease-\(covid-19\)](https://www.who.int/publications/i/item/laboratory-biosafety-guidance-related-to-coronavirus-disease-(covid-19))