WHO CONSORTIUM AND ALLOCATION MODEL

How is the Global Fund ensuring access to COVID-19 diagnostics for countries?

The Global Fund is working closely with key partners, international organizations, governments and technical agencies through a World Health Organization-led Consortium to rapidly and equitably support access to COVID-19 diagnostics for low- and middle-income countries. The Global Fund and UNICEF are the lead procurers for automated molecular COVID-19 diagnostics and have secured production capacity with major manufacturers to operationalize the WHO allocation model and ensure equitable access to the available supplies. The Global Fund is procuring Cepheid and Abbott products, and UNICEF is procuring Thermo Fisher and Roche products. Additionally, WHO is procuring manual COVID-19 diagnostic tests from BGI and Thermo Fisher. The WHO allocation model represents the current total volumes available from these manufacturers to all WHO Consortium-eligible countries, regardless of funding source. The Global Fund, UNICEF and WHO have 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.

How are COVID-19 diagnostic volumes allocated to countries? Will countries with small orders have similar access as larger purchasers?

WHO has designed a worldwide allocation model for products which covers 140 countries. The allocation is based on the WHO Country Office and Africa Centres for Disease Control and Prevention current diagnostic instrument mapping and considers each country’s population, health system vulnerability and testing capacity. WHO has allocated initial volumes from five major manufacturers to countries based on expected product availability and has communicated these volumes through their country offices.

Today, there is significant global demand for these products and supply is limited. Given the challenges in securing these diagnostic products, the Global Fund aims to follow the WHO allocation model for all of its implementing countries and allow the use of grant funds, including C19RM funds, for the purchase of diagnostic products up to the allocated volumes. 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, in line with a country’s registered demand as articulated in their C19RM funding request and/or as submitted to the WHO Supply Portal.
What diagnostic products has the WHO Consortium allocated to countries?

How does my country find out its WHO allocation for COVID-19 diagnostics?
The WHO has communicated allocated volumes through their country offices. Principal Recipients should reach out to their WHO country contacts to receive notifications of their allocated quantities. Principal Recipients should contact the WHO Country Office Finance Officer or alternatively, the Incident Manager / Technical Officer if Finance Officer is unavailable.

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 C19RM funding request and through the WHO Supply Portal.

Can my country purchase additional diagnostic tests for automated platforms in addition to its allocated volumes from current WHO Consortium suppliers (Abbott, Cepheid, Roche, Thermo Fisher, and BGI) using other sources of funding?
No. Domestic or other funds will not enable access to extra volume of allocated products from Consortium suppliers. There is limited global availability of these specific COVID-19 diagnostic tests. The WHO allocation model represents the current total volumes available to 140 countries today, regardless of funding source. The Global Fund, UNICEF and WHO have secured production capacity to cover the volumes of these products in the WHO allocation model. The Global Fund has made sufficient funds available for the diagnostic tests for automated platforms through the C19RM.

Should there be a significant change in the supply situation and major new volumes become available, it is possible that the Consortium may decide to update the allocation model and methodology to ensure equitable allocation of these new volumes.

What options exist if my country is not allocated enough GeneXpert cartridges?
Given the current supply situation for COVID-19 diagnostics, a country’s allocated volumes are likely to be lower than demand. Countries should consider including other compatible molecular diagnostic tests from Thermo Fisher, Abbott or Roche, or including manual diagnostic tests available through the WHO or from other manufacturers in their testing plans.

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 C19RM funding request.

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 considers test volumes already procured directly with manufacturers to ensure there is equitable distribution of tests to countries that have not yet been able to procure tests.
Can my country procure other, non-WHO Consortium allocated COVID-19 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.

Will other COVID-19 diagnostic tests be available to procure through wambo.org?

Today, only Abbott and Cepheid COVID-19 diagnostic tests are available in wambo.org. We are working with UNICEF to bring Thermo Fisher and Roche COVID-19 diagnostic tests on the platform and will keep Principal Recipients updated if and when they become available to purchase through wambo.org.

Over time, the Global Fund may contract 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 COVID-19 DIAGNOSTIC TESTS

Can my country use the existing GeneXpert instrument for COVID-19 diagnostic 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 for HIV and tuberculosis testing on the same instrument to ensure continuity of service for HIV and tuberculosis programs.

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>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><strong>The test and materials needed to run the test:</strong></td>
</tr>
<tr>
<td>The test and materials needed to run the test:</td>
<td>Xpert Xpress kit; cartridges with integrated reaction tubes; disposable transfer pipettes; and CD (assay definition file and instructions).</td>
</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>Materials required for sample collection not included:</td>
<td>Nasopharyngeal swab collection kit</td>
</tr>
<tr>
<td>Nylon swab; viral transport media tube; and ethanol required for TNA extraction.</td>
<td></td>
</tr>
<tr>
<td>Other items not included:</td>
<td>Machines and related warranties, training, installation and calibration</td>
</tr>
</tbody>
</table>

COVID-19 Accelerated Order Mechanism, May 2020
Do I need a Biosafety Cabinet Class-II for COVID-19 diagnostic testing using the Cepheid GeneXpert platforms?

As per the latest WHO Biosafety guidelines 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. 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.

Do Abbott and Cepheid 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 COVID-19 DIAGNOSTIC TESTS THROUGH THE ACCELERATED ORDER MECHANISM (AOM)

How do I purchase COVID-19 diagnostic tests from Consortium suppliers?

The Global Fund is the lead procurer for automated COVID-19 diagnostic tests from Cepheid and Abbott. Countries with a Global Fund grant and approved funding for COVID-19 diagnostic procurement may purchase Abbott and Cepheid diagnostic tests through the Accelerated Order Mechanism (AOM) through the Global Fund’s Supply Operations Department.

Principal Recipients should submit orders for Roche or Thermo Fisher diagnostics directly to UNICEF Procurement Services for now. The Global Fund is working with UNICEF to bring Thermo Fisher and Roche COVID-19 diagnostic tests onto wambo.org and will keep Principal Recipients updated if and when they are available to purchase through wambo.org.

Principal Recipients should submit their orders for manual diagnostic tests directly through the WHO Supply Portal. See WHO’s FAQ on the Supply Portal for more information.

What is the timeline for placing an order through the AOM?

The AOM was designed to be a rapid process to quickly process and approve requests for Abbott and Cepheid COVID-19 diagnostics within three days of receipt of request.

Following the confirmation of “master data” information (e.g., consignee, delivery address, etc.) the Global Fund’s Principal Recipient Services Team will reach out to initiate the order when a Principal Recipient’s C19RM funding request (containing relevant items in Annex 2) is received, but the order cannot be formally processed or issued until the C19RM funding is approved and grant funding has been earmarked in wambo.org. Principal Recipients with approved funding under grant flexibilities may submit a request through wambo.org as soon as funding is confirmed, or, if not registered to wambo.org, may contact their Country Teams to start the order process.
I am unsure about the next step once my country’s funding request is approved. What is the preferred procurement channel by health product, whether I am a Principal Recipient that already uses wambo.org or not?

We hope this table will help clarify. This guidance may change over time, and we will provide updates as needed.

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Already using wambo.org</td>
<td><strong>AOM Process:</strong> Global Fund Supply Operations team will issue a Purchase Requisition to the PR via wambo.org.</td>
<td>PR should contact <a href="https://www.unicef.org">UNICEF Procurement Services</a> directly. Soon, PRs will be able to submit an order directly via wambo.org for UNICEF products and catalogue.</td>
<td>PR should procure through the <a href="https://supply.who.int">WHO Supply Portal</a> or suppliers directly. In the future, it may be possible to order directly through wambo.org.</td>
</tr>
<tr>
<td>No prior history using wambo.org</td>
<td><strong>AOM Process:</strong> Global Fund Supply Operations team will confirm the Purchase Requisition via email with the PR before issuing a Purchase Order to the PSA via wambo.org, on behalf of the PR. There is no need for the PR to access wambo.org.</td>
<td>PR should contact <a href="https://www.unicef.org">UNICEF’s Procurement Services</a> directly.</td>
<td>PR should procure through the <a href="https://supply.who.int">WHO Supply Portal</a> or suppliers directly.</td>
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</table>

**Who should I contact to initiate an order through the AOM?**

Following a positive C19RM Committee Funding Decision that includes a request to procure Abbott or Cepheid molecular COVID-19 diagnostic products, and after confirmation of key information (see question below), the Global Fund’s Principal Recipient Services Team will initiate the procurement process.

A Principal Recipient already using wambo.org who wishes to proactively confirm required information can contact their Supply Operations Principal Recipient Services focal point. Principal Recipients who are not registered in wambo.org can contact their Country Team (Fund Portfolio Manager or Health Product Management Specialist), who will connect you with the appropriate focal point in the Principal Recipient Services Team.

Following an approved 5% flexibility Funding Decision that includes a request to procure Abbott or Cepheid molecular COVID-19 diagnostic products, Principal Recipients registered to wambo.org should submit their request via the platform following the normal wambo.org process. Principal Recipients who are not registered in wambo.org can contact their Country Team (Fund Portfolio Manager or Health Product Management Specialist) for further guidance.

**How do I submit a request for Abbott or Cepheid COVID-19 diagnostic tests through the AOM using either grant flexibilities or approved C19RM funding?**

The AOM is a rapid procurement process that relies on existing Pooled Procurement Mechanism and wambo.org processes, adapted for COVID-19 diagnostic procurement for Abbott and Cepheid diagnostic tests.
Principal Recipients that do not currently have access to wambo.org will not be disadvantaged. An accelerated process that has been developed does not require full onboarding to wambo.org, although the transactions will be processed via the platform.

For Principal Recipients that already use wambo.org, orders for Cepheid and Abbott products with approved grant flexibility funding can be submitted via the wambo.org platform like other wambo.org orders, as soon as the funding is confirmed. If the order is part of a C19RM application (indicated in Annex 2), the Global Fund’s Principal Recipient Services Team will contact the Principal Recipient in due time to confirm basic order information such as delivery addresses, consignee information and incoterm and initiate the order.

The AOM process has already been launched for all Principal Recipients that do not currently use wambo.org, whether the order is funded through the C19RM or approved grant flexibilities. If the order is part of a C19RM application the Global Fund’s Principal Recipient Services Team will contact the Principal Recipient in due time to collect basic order information such as delivery addresses, consignee information and incoterm and initiate the order. If the order is part of an approved grant flexibility, Principal Recipients can contact their Country Team representatives to initiate the order if the Principal Recipient Services Team or Country Team has not already reached out.

Given the increased demand and anticipated order volumes, the accelerated process requires only essential information from Principal Recipients and will be subject to streamlined approvals. Principal Recipients are encouraged to obtain all approvals as quickly as possible to meet the target of issuing a Purchase Order within three days of receipt of request.

Payment will be made directly from the grant from the Global Fund to the Procurement Service Agent (PSA).

Before an order can be issued, the following will be verified:

- **Confirmed funding** through C19RM or 5% flexibility;
- **Grant funds are earmarked** in wambo.org;
- **Quantity per platform** based on WHO allocation output and preferences for delivery schedule;
- **Confirmation of order and delivery master data**, including grant number, recipient name, delivery/consignee address, incoterm, and necessary shipping documents; and
- **Approval of the order**, either through the offline AOM form or through a wambo.org requisition.
What is the AOM process for a Principal Recipient already using wambo.org?

For approved C19RM funding decisions, the Global Fund’s Supply Operations team will create requisitions for Principal Recipients currently procuring through wambo.org based on the verified quantities per platform and standard estimations of logistics costs.

Supply Operations will submit the requisitions via wambo.org to Principal Recipients for approval, according to their established approval processes documented in the wambo.org onboarding form. Principal Recipients are encouraged to complete all approvals in a timely manner to meet the target of issuing the PO in three days. If any changes to the approval chain are required, the Principal Recipient should inform their wambo.org focal point to update the onboarding form. In some cases, the process for PRs not already using wambo.org described below may temporarily be used.

Below is the process for a Principal Recipient using wambo.org:

![Diagram of the AOM process]

For approved 5% flexibility Funding Decisions, Principal Recipients already registered to wambo.org should create and submit the requisition via the wambo.org platform following the normal process.

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 through the Accelerated Order Mechanism. 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 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.
What is the AOM process for a country if they are not registered in wambo.org?

The Global Fund's Supply Operations Department will prefill an offline Order Form with verified quantities per platform, standard estimations of logistics costs, known order and delivery data, and legal conditions, for Principal Recipient completion, approval and signature outside of the wambo.org platform. The Country Team will review and approve the order. Supply Operations then will use the approved form to create a requisition in wambo.org on behalf of the Principal Recipient, which will go through internal controls and result in a Purchase Order being issued to the PSA.

Below is the process for a Principal Recipient not registered to use wambo.org:

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.

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

Once the funding request is approved, 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. We ask that Principal Recipients respond urgently to any inquiries from the Global Fund or Procurement Service Agents.

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

Non-eligible countries should channel orders to the Stop TB Partnership’s Global Drug Facility and PAHOs Strategic Fund.