

Briefing Note

New Pricing for Cepheid GeneXpert Tuberculosis Testing

Date: 19 October 2023

This Briefing Note has been developed to provide the Global Fund Secretariat and in-country partners with information regarding collaboration with Cepheid to increase access to Cepheid's tuberculosis (TB) tests and services.

Background

The Global Fund has recently launched its ambitious new [Strategy \(2023-2028\)](#), which includes the NextGen Market Shaping approach, developed in 2022. Among the key objectives of the approach are: (1) facilitating equitable and sustainable access to quality health products and services; (2) fostering innovation through partnerships; and (3) harnessing synergies to achieve better outcomes.

Key to the fight against TB is access to rapid molecular diagnostic testing. Among TB testing products recommended by WHO, low-complexity Nucleic Acid Amplification (NAAT) automated tests are a class of diagnostics intended for use in initial TB testing. These tests offer rapid confirmation of *Mycobacterium tuberculosis* (MTB) complex and drug susceptibility testing (DST) at central and peripheral health care levels. The products in this class include **Cepheid's GeneXpert**.

In December 2010, WHO endorsed the above-mentioned GeneXpert technology (Xpert® MTB/RIF assay) and released a recommendation and guidance for countries to incorporate the new test into their programs. Xpert Ultra, a test with a higher sensitivity than Xpert MTB/RIF, was released in 2017 and endorsed by WHO in the same year.

In 2012, the Gates Foundation, USAID, PEPFAR and UNITAID signed a 10-year buy-down agreement with Cepheid to reduce GeneXpert TB test costs to US\$9.98 per unit and negotiated reduced prices for the different instrument configurations offered by Cepheid. The expiry of the buy-down agreement provided the opportunity for the Global Fund and

partners to re-engage with the TB community, revisit its approach to the category and closely align its efforts with those of its partners to meet the needs of TB programs.

Following detailed deliberations among partners through a dedicated Technical Task Force, this coalition decided to pool its collective leverage and to launch **joint and parallel direct negotiations** with key suppliers. As a result of negotiations with Cepheid, better commercial terms and improved service and maintenance offerings were achieved, as outlined below.

Outcomes

The outcomes of the negotiations with Cepheid were as follows:

- **Test pricing**
 - **20% reduction** in **MTB/RIF ULTRA** test price, from US\$9.98 to **US\$7.97 per unit**.
 - **25% reduction** in **MTB/XDR** test price, from US\$19.80 to **US\$14.90 per unit**.
- **System pricing**
 - **Reduction** in system costs through two new **bundles** valid in 2023.

Part number	Bundle content	Instrument - only Price (US\$)	Bundle Price (US\$)
PCK-MTB/XDR-50-L	GXIV-4-L-10C + 50 tests MTB/XDR	19,000.00	17,500.00
PCK-MTB/XDR-50-D	GXIV-4-D-10C + 50 tests MTB/XDR	19,000.00	17,500.00

- **Service and Maintenance modalities**
 - **AccessCare** and **Warranty+** are offered using the same service level agreement (SLA), with different payment modality (AccessCare is a surcharge per test, Warranty+ is cost per system).
- **SLA-based expansion of service and maintenance**
 - Cepheid committed to offering **AccessCare** and **Warranty+** to all Global Fund-supported countries (with a small number of exceptions, including embargoed countries), with an eligibility timeline of **five to nine months** and clear eligibility criteria.
- **Simplified pricing**
 - **3-tier pricing** mechanism for **AccessCare** (US\$0.90, US\$1.20, and US\$1.50), based on the number of modules covered and the volume of tests per year (see [Annex 1](#)).

- **Warranty+** offered with same SLA for a 10-color, 4-module instrument at a price of **US\$3,790** per year or **US\$3,500 per year** if on a three-year contract).
- **Standardized transition**
 - Agreed transition to **AccessCare** is managed through **standard terms and conditions** for all countries.
- **Module upgrade**
 - Cepheid to replace failed 6-color modules with a new-generation 10-color module free of charge for modules under warranty and/or AccessCare (where software upgrades can be implemented).
- **Connectivity**
 - C360 software roll-out prioritized in 14 high-burden countries.
- **Training**
 - Two types of training: Training & Installation (based training offered free of charge for countries with ASP) and Super-User training (four days comprehensive training).

Grant-making and placing orders

During grant-making and grant implementation: Principal Recipients (PRs) wishing to procure the Xpert MTB cartridges are invited to contact their Global Fund Country Team to discuss the approach most relevant to the country/grant context, and/or if they require additional support related to the service and maintenance aspects of the contract.

For further information, please contact the Country Team or Pooled Procurement Mechanism (PPM) Focal Point, who can provide specific advice around net pricing and bundle pricing as well as the service and maintenance offering.

Placing orders in wambo.org: All Xpert MTB products (including Xpert MTB/RIF ULTRA kit-10 tests, Xpert MTB/RIF ULTRA kit-50 tests, and Xpert MTB/XDR kit-10 tests) can be requested and ordered in wambo.org at the newly negotiated prices. Other aspects of the new agreement will be facilitated by the Procurement Service Agent during requisition phase.

Questions & Answers

What is the new price for the Xpert MTB/RIF Ultra and the Xpert MTB/XDR cartridges?

The new price for the Xpert MTB/RIF Ultra is US\$7.97, a 20% reduction from the previous price of US\$9.98. The new price for the Xpert MTB/XDR is US\$14.90, a 25% reduction from the previous price of US\$19.80.

Which partners and countries will benefit from the lower pricing? Will Global Fund distribute these tests at the lower cost to all countries?

Pricing is applicable for the Global Fund, Stop TB Partnership, USAID, and all buyers meeting the eligibility criteria of the Cepheid Global Access Program. It is available to all countries supported by the Global Fund.

Eligible organizations in the countries in the following list may access the price list here: <https://www.cephheid.com/en-US/impact/global-access/eligibility-and-pricing.html>

The following types of organizations in eligible countries can access the pricing under Cepheid's Global Access Program:

- Governments or government-funded institutions such as health ministries, associated hospitals, armed forces, or prison services in those countries.
- NGOs and United Nations-related organizations working for or in eligible countries such as Partners in Health (PIH) or UNICEF.
- Non-profit organizations such as Médecins Sans Frontières, Save the Children, OXFAM and the International Committee of the Red Cross (ICRC).
- Global health mechanisms such as the Global Fund, Stop TB Partnership Global Drug Facility, USAID, UNITAID and PEPFAR, and agencies based outside the country but supporting implementation locally in the country, such as the U.S. Centers for Disease Control and Prevention and the International Union Against Tuberculosis and Lung Disease.
- On a case-by-case basis, private organizations recognized by a country's health ministry and whose mission is in line with humanitarian principles.

How long will this new price be valid for?

The offered pricing is valid in line with the duration of the Global Fund framework agreement of two years, with option to be extended. The pricing is valid as of 18 September 2023.

The new pricing was accepted by the Global Fund, Stop TB Partnership and USAID, as it represents a significant reduction of 20% since the original buydown pricing of US\$9.98 established in August 2012.

How will the new pricing be communicated to countries?

The Global Fund will communicate the pricing as “reference pricing” to all countries through its procurement platform wambo.org and by briefing the Country Teams. The pricing will also be reflected in the catalogue of the Stop TB Partnership Global Drug Facility. Additionally, information materials are being developed and shared with countries. An open webinar for national TB programs and other Ministry of Health representatives, Global Fund country implementers, civil society and international partner agencies was organized by the Global Fund, Stop TB Partnership, USAID, WHO and the Bill & Melinda Gates Foundation on 13 October 2023.

How do the Global Fund and its partners ensure a competitive market for TB molecular diagnostics?

The Global Fund and its partners promote accelerated introduction of innovative technologies and advocates for a diversified testing approach by working with partners and countries to develop optimal and diversified national testing strategies that are effective and efficient and that take into consideration all WHO-recommended diagnostics that meet the Global Fund quality assurance criteria.

Can countries that are eligible for the Global Access Program use domestic funds to buy cartridges directly from Cepheid at the reduced prices?

Yes, countries intending to use the cartridges to meet public health needs and that provide the cartridges free of charge through a public health program may benefit from the Cepheid Global Access Program price. To order directly from Cepheid, payment must be made upfront in U.S. dollars. However, national regulations in some countries require payment upon delivery, payment in local currency and procurement only from registered in-country organizations. In such cases, the cost of procurement through in-country authorized distributors may include price markups. Countries may discuss options for procurement through Global Fund’s Wambo or Stop TB Partnership’s Global Drug Facility in order to access the lower prices.

What are the changes in service and maintenance packages offered by Cepheid?

As a result of recently concluded negotiations between Cepheid and the Global Fund, Stop TB Partnership and USAID, Cepheid has committed to offering comprehensive service and maintenance packages in the form of AccessCare or Warranty+ to all Global Fund-supported countries (with a small number of exceptions, including embargoed countries).

AccessCare and Warranty+ are comprehensive service and maintenance packages that include not only replacement modules and parts and XpertCheck kits (as covered by standard warranties) but also on-site visits by an authorized service provider for module swaps, instrument repair, installations, and preventative maintenance. The cost of

AccessCare is a cartridge surcharge (bundling) across all cartridges bought by a Ministry of Health (including for TB, HIV, HCV, HPV, etc); this allows for cost-sharing across programs according to use and facilitates sustainability. The cost of Warranty+ is an annual fee per instrument.

AccessCare and Warranty+ are both executed under an SLA. Countries with AccessCare or Warranty+ receive monthly key performance indicator (KPI) reports on a standard set of metrics that measure the performance of the service provider against targets on timeliness of replacement of modules and other critical parts (computers and gateway boards) and timeliness of annual XpertChecks (module calibration checks), as well as overall uptime of instruments and modules.

The cost of AccessCare has been simplified and comprises three tiers, divided according to average module utilization in a country, i.e., average number of tests performed per module per day. The three costs are US\$0.90, US\$1.20 and US\$1.50 per test. The cost of Warranty+ for a 4-module instrument is US\$3,790 per year, or US\$3,500 per year under a three-year contract.

Countries interested in AccessCare or Warranty+ may reach out to the Global Fund, Stop TB Partnership Global Drug Facility or USAID or directly to Cepheid for more information.

My country has a fleet of GeneXperts with 6-color modules, but 10-color modules are required for use of the Xpert MTB/XDR test. Is there a less expensive option than buying all new modules or instruments?

Cepheid is developing a GeneXpert software update that will allow for hybrid instruments that use both 6-color and 10-color modules. This is expected to be available in the first half of 2024 for use on workstations (desktops or laptops) that can accept the software update. When the software update has been executed, for instruments that are under Warranty+ or AccessCare, Cepheid has agreed to provide refurbished 10-color modules when 6-color modules require replacement at the time of XpertCheck or other failure.

Furthermore, countries can currently avail themselves of a bundle offer from Cepheid that provides a 4-module, 10-color instrument at the price of a 4-module, 6-color instrument (US\$17,500) plus 50 Xpert MTB/XDR tests free of charge. This bundle offer is available until the end of 2023.

What types of training does Cepheid offer?

Cepheid offers two types of training: basic training on the use of the GeneXpert instrument at time of installation (offered free of charge for countries with a Cepheid representative or a Cepheid-authorized service provider) and super user training (four days of comprehensive training). For details on the scope of the offered training, countries may contact the Global Fund, Stop TB Partnership Global Drug Facility, USAID or Cepheid directly for more information.

Annex 1: AccessCare Tier Pricing

AccessCare surcharge estimation table

AccessCare surcharge estimation table

Volume of Tests	ISB (Module to cover) - SLA 1 year																
	100	200	300	400	500	750	1,000	1,250	1,500	1,750	2,000	2,500	3,000	3,500	4,000	4,500	5,000
4,000,000	N/A													\$ 0.90	\$ 0.90	\$ 0.90	\$ 1.20
3,000,000												\$ 0.90	\$ 0.90	\$ 0.90	\$ 1.20	\$ 1.20	\$ 1.20
2,500,000											\$ 0.90	\$ 0.90	\$ 0.90	\$ 1.20	\$ 1.20	\$ 1.50	\$ 1.50
2,000,000									\$ 0.90	\$ 0.90	\$ 1.20	\$ 1.20	\$ 1.20	\$ 1.20	\$ 1.50	\$ 1.50	
1,500,000							\$ 0.90	\$ 0.90	\$ 0.90	\$ 1.20	\$ 1.20	\$ 1.50					
1,250,000						\$ 0.90	\$ 0.90	\$ 0.90	\$ 1.20	\$ 1.20	\$ 1.50						
1,000,000						\$ 0.90	\$ 1.20	\$ 1.20	\$ 1.20	\$ 1.50							
750,000					\$ 0.90	\$ 1.20	\$ 1.20	\$ 1.50									
500,000			\$ 0.90	\$ 0.90	\$ 1.20	\$ 1.50											
400,000			\$ 0.90	\$ 1.20	\$ 1.50												
300,000			\$ 0.90	\$ 1.20	\$ 1.20												
200,000		\$ 0.90	\$ 1.20	\$ 1.50													
150,000		\$ 1.20	\$ 1.50														
100,000	\$ 0.90	\$ 1.50															
50,000	\$ 1.50																
40,000																	
35,000																	