FAQ: All-Inclusive Testing Price Agreement for Hologic Panther® System

On July 25, 2018, Hologic, Inc., MedAccess, Unitaid, the Clinton Health Access Initiative, Inc. (CHAI) and partners, announced a breakthrough pricing agreement to significantly reduce the cost of diagnostic testing for HIV/AIDS, hepatitis and cervical cancer for more than 180 million individuals living in low- and middle-income countries. Subject to certain minimum volume requirements, the new agreement enables public-sector programs in 49 countries in Africa, Southeast Asia and Latin America to access the Hologic Panther system, an integrated molecular diagnostic instrument, at an all-inclusive price of US $12.00 per patient test with no upfront costs or capital expenditure. The new testing platform will generate faster results for patients and increase adherence to treatment at a significantly reduced price.[1]

Improving Access

Why is the Panther system an improvement over current technologies in resource-limited settings?

The Panther system is a market-leading, integrated platform that fully automates molecular testing with true sample-to-result automation, adaptable workflow options and a consolidated testing menu. In countries where coinfection is most prevalent, the Panther system and Aptima® virology and HPV assays offer the opportunity to simultaneously run multiple tests from one patient sample, improving lab productivity, accelerating results and, ultimately, enhancing patient care.

The Panther system requires the lowest hands-on labor time of any comparable molecular diagnostic platform while simultaneously offering the highest output volume per square meter – up to 320 results in 8 hours in less than one square meter of space.[2,3] Designed to be both modular and scalable, the Panther system accommodates the needs of both large centralized labs and smaller decentralized labs.

How will this agreement support HIV viral load scale-up and meet the 95-95-95 UNAIDS 2030 goal?

The World Health Organization (WHO) has recommended molecular diagnostic viral load testing as the gold standard for monitoring the effectiveness of antiretroviral therapy (ART) since 2013.[4] However, despite prioritization by donors, governments and partner organizations, coverage in low- and middle-income countries remains critically low, with only 59% of people on ART having routine access to viral load testing.[5] The UNAIDS 2030 95-95-95 targets call for 95% of all people receiving ART to have viral suppression by 2030, which will require significant scale-up to close the gap.[6]

The agreement applies to an estimated 95% of people living with HIV in low- and middle-income countries and takes an important step towards ensuring the sustainability and affordability of HIV viral load testing services.[6] The savings generated from the agreement will allow governments to accelerate scale-up to improve treatment monitoring for hundreds of thousands of patients.[1]

What is the all-inclusive testing price?

The all-inclusive testing price is US $1,128.00 per 100 test kit unit, which is equivalent to $12.00 per patient test. Each kit includes 100 tests, 94 of which can be used to process patient samples (6 tests are needed for control and calibration purposes).

What is included with the all-inclusive testing price?

The all-inclusive testing price consists of all supplies and services needed to generate a patient result, including: instrument placement, reagents and consumables, service and maintenance, freight and logistics and replacement tests (for one set of controls and calibrators and documented instrument errors).

Category	Description
A - Instrument Placement	Equipment needed to process samples placed free of charge; including site inspection, installation, basic connectivity and ongoing training.
B - Reagents & Consumables	All reagents and consumables needed to produce a test result including controls, calibrators and all supplies needed to process dried blood spot (DBS) samples.
C - Service & Maintenance	Cost of servicing and maintaining the Panther® system and related equipment, including preventative maintenance, repairs and replacements and any necessary modifications and/or updates.
D - Freight & Logistics	Delivered at place (DAP) to the testing site or national warehouse. Includes cost of export fees, clearance, carriage, insurance, port charges and distribution (excludes import customs clearance, post-carriage and unloading at destination point).
E - Control & Calibration	The cost of assays used for control and calibration purposes that do not produce a patient result is factored into the all-inclusive price (6 per test kit). Tests used for control and calibration purposes, beyond one run per kit, are the responsibility of the customer.
F - Errors & Failures	Free-of-charge replacement of tests that fail due to documented instrument errors; and corrective action training for labs with high rates of user errors.

What is not included under the global all-inclusive testing price?

The all-inclusive testing price does not include ancillary costs, for example those associated with sample collection, sample transport, laboratory staff time, laboratory infrastructure, generic lab supplies (e.g. primary collection tubes, disposable gloves, bleach, bleach bottles, bleach enhancer, waste bottles, etc.), inventory management, or general administration and overhead costs. The all-inclusive testing price does not include the following additional equipment necessary to run the tests: centrifuge, vortex mixer and pipettor.

What is the duration of the all-inclusive testing price agreement?

The all-inclusive testing price agreement will be in effect for a 4-year period. After this period, the all-inclusive testing price is expected to remain the same, subject to assessment of current testing volumes.

Tests for which diseases are covered in the all-inclusive testing price agreement?

Tests for HIV, HCV, HBV and HPV are included in the agreement. Specifically, the eligible tests, or assays, are the Aptima® HIV-1 Quant Dx Assay, Aptima® HCV Quant Dx Assay, Aptima® HBV Quant Assay and Aptima® HPV Assay (100 test kit format only).

All-Inclusive Testing Price Eligibility

Which countries are eligible to access the terms of the all-inclusive testing price agreement?

Subject to certain minimum volume requirements, the following countries are eligible:

Angola
Benin
Botswana
Burkina Faso
Burundi
Cambodia
Cameroon
Cape Verde
Central African Republic
Comoros
Congo
Democratic Republic of the Congo (DRC)
Egypt
Eswatini
Ethiopia
Gambia
Ghana
Guinea
Guinea-Bissau
Haiti
India
Indonesia
Ivory Coast
Kenya
Laos
Lesotho
Liberia
Malawi
Malaysia
Mali
Mauritania
Mongolia
Mozambique
Myanmar
Namibia
Nepal
Nigeria
Pakistan
Papua New Guinea
Rwanda
South Africa
Sri Lanka
Tanzania
Timor-Leste
Togo
Uganda
Vietnam
Zambia
Zimbabwe

How were these countries chosen?

Countries were selected based on burden of disease, qualification as a lower- or middle-income country (based on WHO and World Bank criteria) and ability for Hologic (and partners) to engage in commercial activity (e.g., political stability, appropriate infrastructure, qualified local agent for representation, country regulatory status for the relevant assay(s) (i.e., is local regulatory approval or registration required), etc.).

Will other countries eventually be able to take advantage of this agreement?

Additional countries may be added to the list if they satisfy the necessary eligibility and volume requirements and if agreed upon by MedAccess and Hologic.

Which purchasers are eligible to access the terms of the all-inclusive testing price agreement?

Any organization or entity that is purchasing testing services on behalf of public-sector patients in the eligible countries, including procurement agents, government agencies, non-governmental organizations (NGOs) and similar organizations.

Are there any volume requirements associated with the all-inclusive testing price agreement?

If the instrument and relevant assay(s) being registered are available for use in an eligible country, Hologic will place an instrument at any testing site that satisfies the necessary infrastructure requirements, provided processing volumes on that instrument are anticipated to meet or exceed 10,000 patient samples per year and contribute to a national average of 30,000 patient samples per instrument per year. These volume targets are inclusive of all eligible assays and sample types and allow for a scale-up period of 12 months from when the instruments are first installed.

In eligible countries, where the instrument and relevant assays are not already registered, Hologic will file for registration provided that total national processing volumes are anticipated to exceed 60,000 patient samples annually with a minimum national average of 30,000 patient samples per instrument per year.

What if an eligible country does not meet the volume requirements for placement of an instrument?

If an eligible country does not meet the volume requirements specified under the Hologic Global Access Initiative, then interested purchasers and/or representatives from the Ministry of Health should reach out to Hologic (humancare@hologic.com) to discuss the situation and determine a reasonable way forward.

Implementation

How can countries take advantage of this agreement?

Eligible countries interested in introducing the Panther® system for the first time should contact Hologic directly to discuss next steps.

Eligible countries in which Panther instruments are already installed have the option of accessing the terms of the Global Access Initiative for relevant assays for any future orders placed on behalf of mutually agreed upon eligible labs. In order to access these terms, the Ministry of Health or applicable purchaser should contact Hologic (humancare@hologic.com) to discuss how to implement the agreement.

Note: the all-inclusive testing price will not be extended to the currently installed base in an eligible country in cases where the Global Access Initiative volume requirements are not met.

What are the key service terms associated with the all-inclusive testing price agreement?

For all eligible labs covered under this agreement, Hologic commits to an average mean response time of less than 24 hours, an average mean repair time of less than 48 hours and a total system uptime of at least 95% as measured on an annual basis. Hologic and its distributors have developed a master service level agreement (SLA) template that enumerates all service level obligations and performance standards that the service provider is expected to meet. The SLA template is available upon request at humancare@hologic.com.

Are there any site-level infrastructure requirements that must be met prior to installation?

Each testing site must meet the following minimum infrastructure requirements: a) floor space to accommodate an instrument with dimensions 122 cm (width) x 81.5 cm (depth) x 175 cm (height), b) bench or tabletop space to accommodate a rocker and centrifuge, c) an electrical connection that can support up to a 1400 W draw and a dedicated 20-amp circuit, d) a backup generator capable of supporting all of the equipment, e) central or wall-mounted air conditioning with adequate capacity to maintain an ambient temperature between 15°C and 30°C in the laboratory space (and relative humidity between 20% and 85%), f) a sink or washbasin for disposal of liquid waste, g) access to one or more refrigerators with temperature control (2°C – 8°C) to store patient samples and assays corresponding to the expected throughput, and h) access to one or more freezers with temperature control (-15°C to -35°C) to store calibrators and controls corresponding to the expected throughput. Hologic will provide a UPS and surge protector but shall not bear any costs associated with renovations or infrastructure upgrades.

What if a country prefers delivery to its national warehouse instead of the individual testing sites?

The International Commercial Term, or Incoterm, associated with the all-inclusive testing price is DAP to the testing site or alternative site as reasonably requested by the customer (Incoterms 2010). When the order is placed, the customer may request that reagents and consumables be delivered directly to the central medical storage facility so long as proper cold chain capacity exists within the national supply chain to protect the integrity of the product during the shipment process.

Can data from the Panther® system be integrated into existing laboratory information management systems?

The Panther instrument can exchange information with a host computer in the laboratory via RS232 or TCP protocol. The Panther system has bi-directional communication capabilities (i.e. the Panther system can send information to and receive information from the LIMS, assuming the data is structured appropriately). For additional technical details on the Hologic Panther LIS communication protocol, please reach out to humancare@hologic.com.

Under the Hologic Global Access Initiative, the all-inclusive testing price includes establishing 'basic connectivity' for the Panther system, which means establishing a connection to the laboratory's network upon installation and enabling the export of all testing data to a hard drive or server in the necessary file format. If requested by the customer, Hologic (and partners) can develop a middleware software solution to enable automatic uploading of all data to a centralized dashboard or laboratory information management system. Such a middleware software solution would be at a separate cost payable by the customer.

Regulatory

What is the regulatory status of the Aptima® HIV-1 Quant Dx Assay?

The Aptima HIV-1 Quant Dx Assay is CE certified and WHO Prequalified for use as an aid in the diagnosis of HIV-1 infection and clinical management of patients infected with HIV-1. This applies to plasma specimens from whole blood collected in ACD or EDTA, SST or PPT tubes. The assay is also CE certified for DBS specimens for both viral load monitoring and early infant diagnosis (EID). Additional in-country approval or registration may also be required in certain instances before the Aptima HIV-1 Quant Dx assay would be available for shipment to certain eligible countries.[7,8]

What is the regulatory status of the other eligible assays?

The Aptima® HCV Quant Dx assay, Aptima® HBV Quant assay and Aptima® HPV assay are all CE certified. Additional in-country approval or registration may also be required in certain instances before these assays would be available for shipment to certain eligible countries.

Is EID currently available on the Panther system platform?

Hologic has received CE certification for EID using DBS on the Panther system platform.[8]

Technology

Which levels of the health system are most suitable for deployment of the Panther® system?

Depending on laboratory infrastructure, the Panther system is appropriate for Tier 5 (reference laboratories), Tier 4 (central hospital laboratories) and even some Tier 3 (provincial hospital laboratories) facilities.

How many different Aptima® assays can be run on the same sample?

The Panther system allows for the three Aptima® viral load assays (HIV, HBV, HCV) to be run from the same patient sample if an adequate volume of plasma is available.

What are the hands-on time and workflow requirements?

The Panther system is a fully-automated, sample-to-result instrument. With consumables and reagents loaded, up to 120 samples can be processed with no user intervention, providing complete walkaway automation. Hands-on time consists of reagent preparation, sample loading, reagent loading and loading of consumables.[3]

What is the total processing time?

Time-to-first result is 2.7 hours with an additional 5 results available every 5 minutes thereafter. The Panther system processes samples in a continuous, random access manner with up to 320 results in an 8-hour shift.[3]

Is there any toxic waste associated with the Panther system?

There is no toxic waste associated with the Panther system.[3]

Does the all-inclusive testing price include all materials needed to process DBS samples?

Yes, the all-inclusive testing price includes Hologic's Aptima® DBS Kit, which contains the Aptima® DBS Extraction Buffer, Aptima® Specimen Aliquot Tubes (SATs) and transport tube caps for the specimen aliquot tubes (SATs). The price does not include DBS cards. Once DBS is an approved sample type for use in a particular eligible country, purchasers will need to indicate the anticipated breakdown of plasma and DBS samples when placing orders under the program for HIV test kits.

Can primary sample collection tubes be run directly on the Panther system?

Yes, the Panther system can take ACD, EDTA, PPT, SST and serum tubes. Non-proprietary tubes with the following dimensions can be run on the system:

- 13mm x 100mm
- 13mm x 75mm
- 16mm x 100mm

Specimens transported in cryotubes must be transferred into appropriate tubes at the lab that fit into the Panther system racks. The all-inclusive testing price agreement includes SATs for this purpose.

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Contact Information

Who should be contacted for any questions regarding the technology and all-inclusive testing price agreement?

Requests for additional information should be addressed to humancare@hologic.com.

References: 1. Breakthrough agreement will reduce costs and increase access to diagnostic technology for millions in low- and middle-income countries [press release]. Amsterdam, Netherlands: Clinton Health Access Initiative; July 25, 2018. **2.** Ratnam S, et al. Workflow and Maintenance Characteristics of Five Automated Laboratory Instruments for the Diagnosis of Sexually Transmitted Infections. *J Clin Microbiol*. 2014;52(7); 2299-2304. **3.** Panther System Operator's Manual [package insert]. AW-17791-001, San Diego, CA: Hologic, Inc.;2010-2018. **4.** WHO. Technical and Operational Considerations for Implementing HIV Viral Load Testing. Interim Technical Update July 2014. **5.** Clinton Health Access Initiative. 2018 HIV Market Report. The state of the HIV market in low- and middle-income countries. https://clintonhealthaccess.org/the-state-of-the-hiv-market-in-low-and-middle-income-countries/. Published September 12, 2018. Accessed June 25, 2019. **6.** UNAIDS. People living with HIV (all ages) – by region. https://aidsinfo.unaids.org/. 2018 estimates. Accessed June 25, 2019. **7.** Aptima HIV-1 Quant Dx Assay [package insert]. AW-11853, San Diego, CA: Hologic, Inc.; 2019. **8.** Dried Blood Spot (DBS) Supplement to the Aptima HIV-1 Quant Dx Assay [package insert]. AW-17780, San Diego, CA: Hologic, Inc.; 2019.