



# Affordability of Screen and Treat Tools for Cervical Cancer

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*Prepared as part of program supported by Unitaid*



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## **1** HPV Testing

- Background
  - Existing Landscape
  - Available global pricing & analysis
  - On-the-ground observed costs
  - Future efforts
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# Current guidance from WHO has recommended HPV testing as a primary screening modality, however limitations such as pricing and infrastructure may impact scalability

## Cervical Cancer Screening

### Molecular

- A. Nucleic Acid tests (NAT)**
  - HPV DNA
  - mRNA
- B. Protein biomarkers**
  - HPV antibodies
  - Oncoproteins

### Cytologic

- A. Conventional PAP smear**
- B. Liquid-based cytology (LBC)**

### Visual Inspection

- A. Visual Inspection with Acetic Acid or with Lugol's Iodine (VIA / VILI)**
- B. Digital Imaging Approaches**
  - i.e. Automated visual evaluation (AVE)

Through the rapid expansion of TB and HIV testing programs, and more recently through COVID-program expansions, testing infrastructure has expanded greatly across Low-and-Middle-Income countries

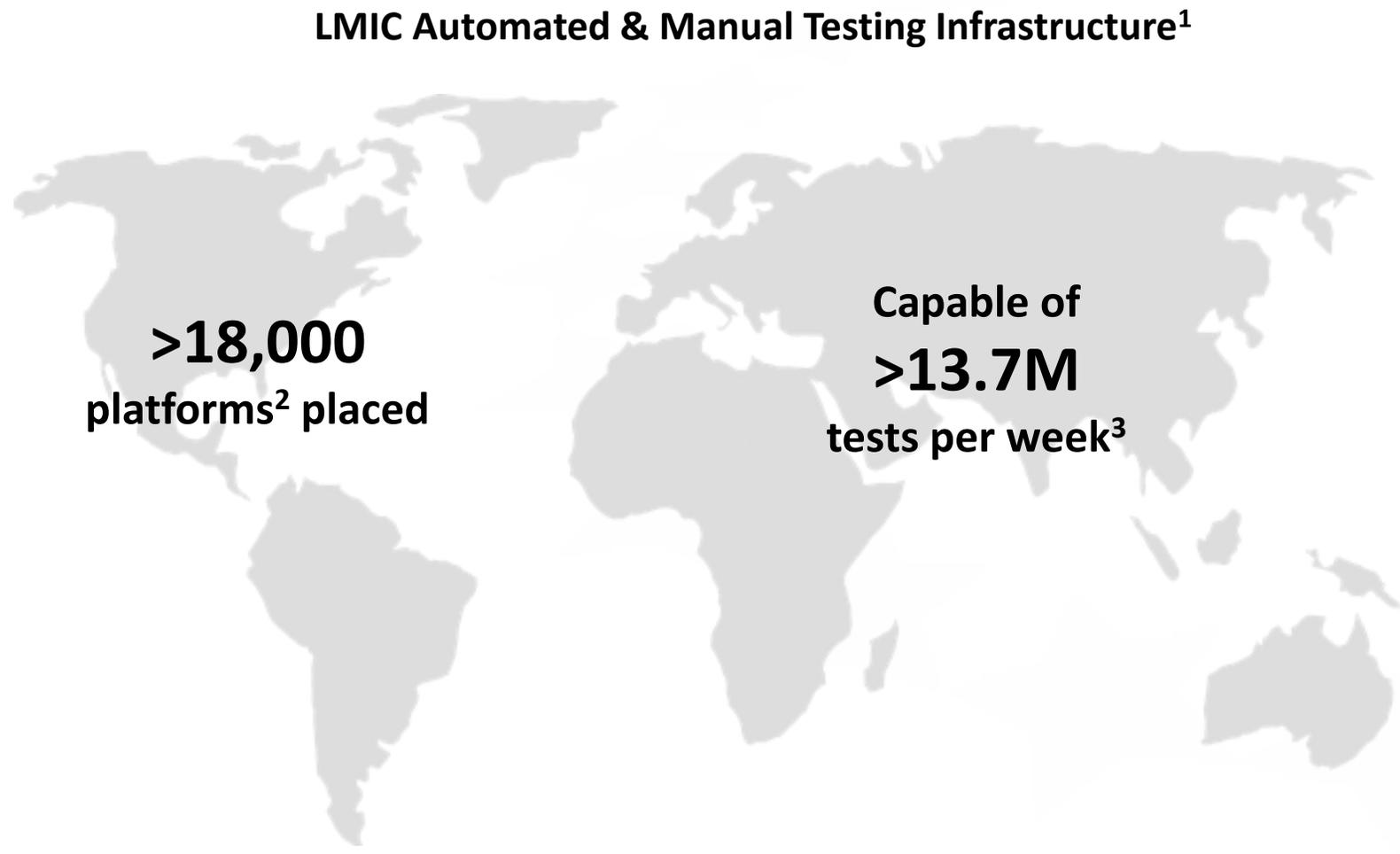


### Key PCR Platforms with HPV Tests

Abbott Laboratories (USA)	Becton Dickinson (USA)
Hologic (USA)	Roche (Switzerland)
ThermoFisher (USA)	Qiagen (USA)
MolBio (India)	Cepheid (USA)

*Not comprehensive*

- Centralized
- Near Point-of-Care

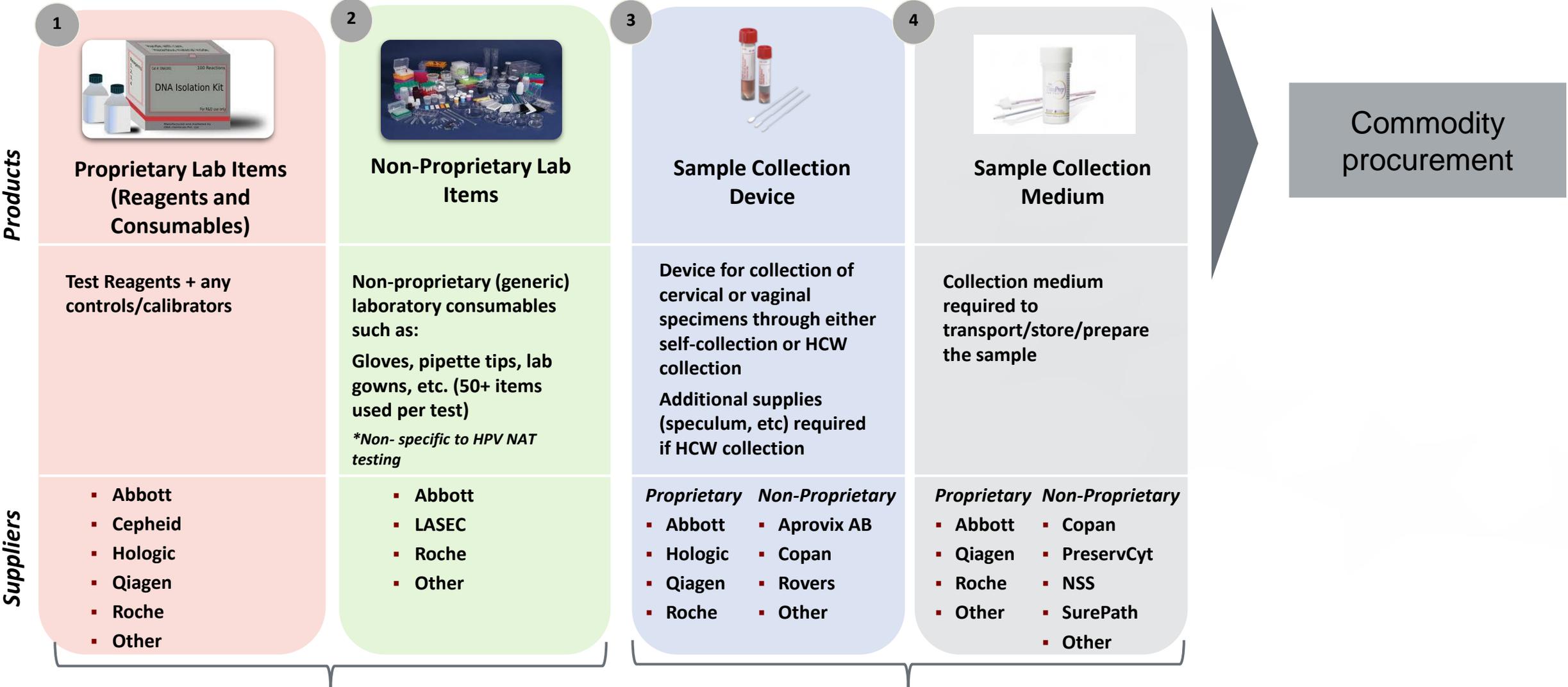


1. Non-comprehensive mapping of footprint data. Data as of February 2023. 2. Platforms indicative of individual amplification platforms (thermocycler, automated amplification platform, GeneXpert I, II, IV, XVI, etc). Gx data based on platform devices assumes average of 4 modules/platform. 3. Capacity calculations based on observed manual testing throughput during Covid period through May 2021, supplier estimated testing throughput for GeneXpert & other automated devices, observed number of shifts per days & days per week for lab operation observed through May 2021. 4. Multiple platform offerings for both centralized & near-POC. 5. Cepheid Edge HPV products in pipeline. 6. Currently available in India, though not yet available globally

# Pricing remains a key barrier to scale, with various key components for HPV testing driving overall pricing: test reagents and consumables, instrument, sample collection media and swabs, etc.



In order to run HPV NAT tests, 4 main types of commodities need to be procured from suppliers.



# Pricing can best be compared by accounting for all additional costs associated with providing a patient with an actionable result

In order to run HPV NAT tests, 4 main types of commodities need to be procured from suppliers.



**Commodity Procurement**

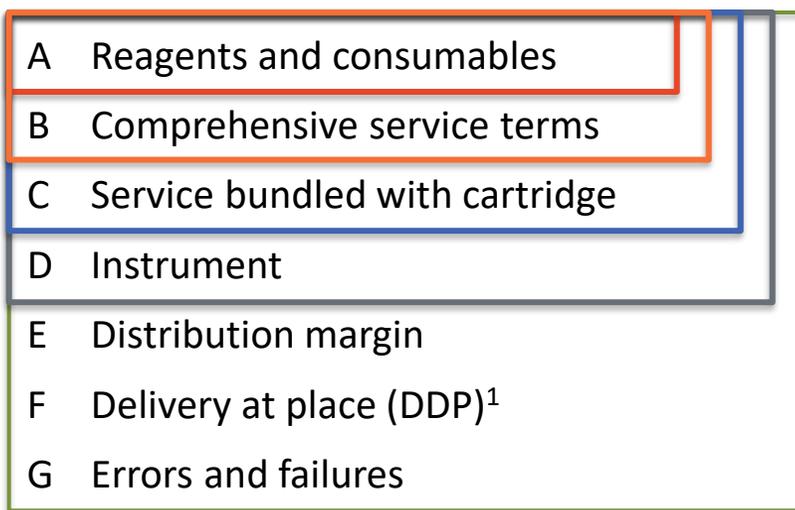
**Additional Costs**

- Service & Maintenance
- Instrument
- Distribution margin
- Freight and Logistics
- Errors and failures

**Total Cost**

# Pricing should be analyzed as a comprehensive “all-inclusive price per patient result” taking into account all costs needed to provide a patient with an actionable result

Components to produce a molecular diagnostic test result, grouped by price agreement



**All-inclusive pricing**

*\* Sample collection priced separately as a non-proprietary product*

- A Standard (default)**  
All components sold separately. Instrument purchased outright; separate purchasing of reagents, consumables, S&M, etc.
- A B C Bundled**  
Single price per test that includes reagents, consumables and S&M
- A B C D Reagent Rental or Placement**  
Instrument rented or placed; Single price includes reagents, consumables, comprehensive service terms, and the incremental cost of the instrument (if applicable); often linked to a volume commitment
- A B C D E F Price per Test (PPT)**  
Single price includes instrument placement, comprehensive service terms, and reagents and consumables (DDP).<sup>1</sup> Only agreement to provide assays performed for calibration or control purposes free of charge.
- A B C D E F G Price per Patient Result (PPR)**  
Inclusive of all Price-per-Test components with the inclusion of errors and failures.

Standard	Bundled	RR / Placement	Price Per Test	Per Patient Result
<ul style="list-style-type: none"> <li>Instrument downtime</li> <li>Operational complexity</li> <li>High costs and price variability</li> </ul>	<ul style="list-style-type: none"> <li>Ensure every instrument is covered by warranty</li> <li>Simplifies budgeting and procurement</li> </ul>	<ul style="list-style-type: none"> <li>Incentivizes higher instrument use</li> <li>Simplifies budgeting &amp; procurement</li> </ul>	<ul style="list-style-type: none"> <li>Incentivize maximum instrument use</li> <li>Reduce or eliminate hidden costs</li> </ul>	<ul style="list-style-type: none"> <li>Incentivize maximum instrument use</li> <li>Reduce or eliminate hidden costs</li> </ul>

<sup>1</sup>Delivery Duty Paid (DDP) represents maximum responsibility for both costs and risk assumption from beginning to end to the seller. Seller assumes all the risks and costs of transport (export fees, carriage, insurance, and destination port charges, delivery to the final destination) and pays any import customs/duty.

# Pricing availability for HPV tests offered across platforms with significant existing platform footprint in LMICs

*Inclusivity and INCOTERMS vary. Pricing shown here is not directly comparable*

**Abbott**

**HPV \$6.24** <sup>2</sup> EXW

33 SSA countries

**Roche**

**HPV \$7.90** <sup>3</sup> CPT

89 LMICs

**Hologic** <sup>1</sup>

**HPV \$9.00** DAP

8 African countries <sup>4</sup>

**Cepheid** <sup>5</sup>

**HPV \$14.90** EXW

145 countries

## HPV Test Access Learnings

- **For centralized tests, pricing offered is equal or lower, than those of higher-volume HIV and TB tests**<sup>6</sup>
- **Pricing offered by Cepheid has not achieved price parity with TB test offers**
- **Lower pricing has been offered** to specific countries or programs where clear, funded demand is available
- **High variation in landed costs** (*shipping costs, distributor margins, etc*) creates challenges for governments considering the transition / scale-up of HPV

<sup>1</sup> All-inclusive

<sup>2</sup> Instrument included \$7.99

<sup>3</sup> Pricing for <50k tests, \$6.90 for 50-250k, and \$5.90 >250k

<sup>4</sup> \$11.28 all-inclusive pricing available to 50 countries; \$6.90 reagent-only FCA pricing also available

<sup>5</sup> Part of all-in GX 16 program

# Global access prices (GAP) offered by suppliers demonstrate a diverse set of accessible pricing agreements

Conventional

Near Point-of-Care



Assay	RealTime High Risk (HR) HPV		Alinity m (HR) HPV		Aptima HPV	cobas® 4/6/8800 HPV	Xpert HPV	careHPV
Platform	m2000 sp/rt		Alinity m		Panther	4/6/8800	GeneXpert (IV, XVI) <sup>1</sup>	careHPV
Manufacturer/ Developer	Abbott		Abbott		Hologic	Roche	Cepheid	Qiagen
Test Target	HPV DNA Target Amplification		HPV DNA Target Amplification		HPV mRNA Target Amplification	HPV DNA Target Amplification	HPV DNA Target Amplification	HPV DNA Signal Amplification
Regulatory Approval	WHO PQ		CE-IVD		FDA / CE-IVD (Dossier submitted to WHO PQ)	WHO PQ	WHO PQ	WHO PQ
Per Test Pricing (Global)	\$6.24	\$8.49	\$6.24	\$8.49	\$11.28 / \$9.00	\$7.90 <sup>3</sup>	\$14.90	\$4.95
Items included in Price	Reagents Only	Reagents, Controls, Instrument	Reagents Only	Reagents, Controls, Instrument	Reagents, Controls, Instrument, Service & maintenance	Reagents Only	Reagents Only	Reagents Only
Incoterm	FCA Wiesbaden		FCA Wiesbaden		DAP	CPT	Ex-works	Ex-works
Pricing Accessibility	33 Sub-Saharan African Countries <sup>2</sup> <i>Other countries may be added on an ad hoc basis</i>		10 Sub-Saharan African Countries <sup>4</sup> <i>Other countries will be added pending regulatory approval</i>		\$11.28: <a href="#">50 Global Access Initiative Countries</a> \$9.00: 8 African countries <sup>5</sup>	<a href="#">84 Global Access Program Countries</a>	<a href="#">145 Eligible Countries</a>	Global availability
Instrument Cost	~\$165,000	Included in price per test	~\$299,000	Included in price per test	Included in price per test	cobas® 4800/5800: ~\$120,000 cobas® 6800: ~\$300,000 cobas® 8800: ~\$600,000	\$19,000 (Gx IV)	\$15,839 - \$22,629
Company Contacts	Francesco Marinucci, Director, Global Market Access & Funding (francesco.marinucci@abbott.com)				Tiffany Clarke, Director, Marketing Virology and Global Health (Tiffany.Clarke@hologic.com)	Joni Zurawinski, Sr PM, Business Development & Strategy (joni.zurawinski@roche.com)	Philippe Jacon, Senior Vice President, Global Access (Philippe.Jacon@cepheid.com)	Mark Destito, Vice President, Global Health (Marc.Destito@qiagen.com)

[Link to Pricing Database](#)

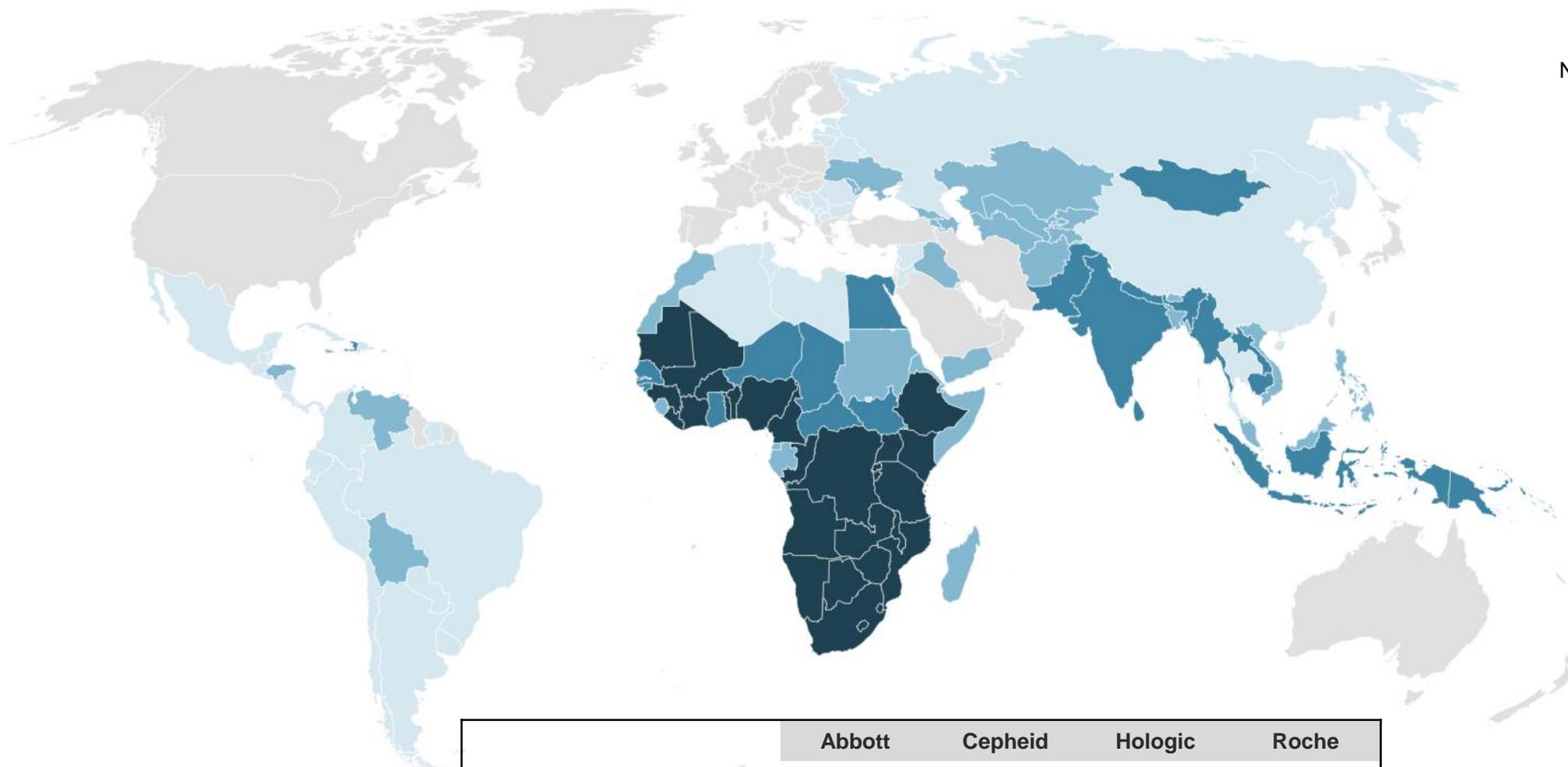
1. Other GeneXpert models include Infinity-48 and Infinity-80. To be available soon on GeneXpert Edge  
 2. \*FCA Incoterm: \*Angola, \*Benin, \*Burkina Faso, \*Burundi, \*Cameroon, \*Chad, \*Congo, \*DRC, \*Ethiopia, \*Guinea, \*Ivory Coast, \*Kenya, \*Liberia, \*Malawi, \*Mali, \*Mauritania, \*Mauritius, \*Mozambique, \*Niger, \*Nigeria, \*Rwanda, \*Senegal, \*South Sudan, \*Tanzania, \*Togo, \*Uganda, \*Zambia, \*Zimbabwe, \*\*DAP Incoterm: \*\*Botswana, \*\*Eswatini, \*\*Lesotho, \*\*Namibia, and \*\*South Africa  
 3. Different prices may apply for special projects/grants, please contact Roche directly. Pricing per test shown for reagents, consumables and controls only; does not include collection devices and other surcharges (eg: instrument placement, instrument service, freight/logistics fees, distributor fees)  
 4. \*FCA Incoterm: \*Kenya, \*Malawi, \*Uganda, \*Tanzania, \*Mozambique, DAP Incoterm: \*\*Botswana, \*\*Eswatini, \*\*Lesotho, \*\*Namibia, and \*\*South Africa  
 5. Eswatini, Kenya, Mozambique (DDP Incoterm), Nigeria, Tanzania, Uganda, Zambia, and Zimbabwe

**Note: Supplier list not exhaustive, showing suppliers with WHO PQ and/or submitted dossiers for WHO PQ. Technical specifications are not presented but should be closely considered when implementing assays.**

# When accounting for additional costs including sample collection, instrument, service and maintenance, and supply chain, estimated costs increase by \$1-\$6

<i>Indicative estimates</i>	Abbott <i>RealTime High Risk (HR) HPV</i>		Abbott <i>Alinity m (HR) HPV</i>		Hologic <i>Aptima HPV</i>	Roche <i>cobas 4/6/8800 HPV</i>	Cepheid <i>Xpert HPV</i>	Qiagen <i>careHPV</i>
<b>HPV Test (supplier price)</b>	<b>\$6.24</b>	<b>\$8.49</b>	<b>\$6.24</b>	<b>\$8.49</b>	<b>\$9.00</b>	<b>\$7.90</b>	<b>\$14.90</b>	<b>\$4.95</b>
<b>Laboratory Costs</b>								
Reagents & proprietary consumables	✓	✓	✓	✓	✓	✓	✓	✓
Controls	✓	✓	✓	✓	✓	✗	N/A	✗
Instrument placement <sup>2</sup>	✗	✓	✗	✓	✓	✗	✗	✗
Service and maintenance <sup>2</sup>	✗	✓	✗	✓	✓	✗	✗	✓
Invalid results due to instrument errors	✗	✓	✗	✓	✓	✗	✗	✗
<b>Supply Chain Costs (incoterms)</b>								
	FCA	FCA	FCA	FCA	DAP	CPT	Ex-works	Ex-works
Pre-carriage & Export customs clearance	✓	✓	✓	✓	✓	✓	✗	✗
Freight	✗	✗	✗	✗	✓	✓	✗	✗
Logistics/Local Distribution	✗	✗	✗	✗	✓	✗	✗	✗
Distributor and local agent fees	✗	✗	✗	✗	✓	✗	✗	✗
Import duty / Taxes	✗	✗	✗	✗	✗	✗	✗	✗
<b>Total Lab &amp; Supply Chain Costs (All-Inclusive)<sup>1</sup></b>	<b>\$7.87</b>	<b>\$10.82</b>	<b>\$7.87</b>	<b>\$10.77</b>	<b>\$9.56<sup>6</sup></b>	<b>\$9.12</b>	<b>\$18.41</b>	<b>\$6.57</b>
<b>Sample Collection<sup>3</sup></b>	<b>\$1.00</b>	<b>\$1.00</b>	<b>\$1.18</b>	<b>\$1.18</b>	<b>\$0.50</b>	<b>\$2.00</b>	<b>\$2.95</b>	<b>\$2.77</b>
<b>Total Cost *</b>	<b>\$8.87</b>	<b>\$11.82</b>	<b>\$9.05</b>	<b>\$11.95</b>	<b>\$10.06</b>	<b>\$11.12</b>	<b>\$21.36</b>	<b>\$9.34</b>

# Negotiated pricing for HPV are available to LMICs and other high-burden countries throughout the world



Number of pricing agreements accessible by country

- One (52)
- Two (41)
- Three (23)
- Four (28)
- None

	Abbott	Cepheid	Hologic	Roche
# Countries Accessing Pricing <sup>1</sup>	33 SSA	145	50 <sup>2</sup>	89 LMICs
% Countries with footprint accessing pricing deals	50%	100%	56%	86%

<sup>1</sup> \$11.28 available to 50 countries; \$9 available to 8 SSA Countries

Focused negotiations at country levels have allowed for significantly improved pricing that can be accessed by countries through setting screening targets, engagement with suppliers, and fostering competition in the market

## CHAI-Supported Countries



## Average costs paid\*

Average HPV  
Test Cost

**\$8.81 per test**

Calculated All-  
inclusive Cost

**\$9.82 per test**

\* Average prices paid from 2019-1H 2021 HPV test procurement through Unitaid-funded Cervical Cancer grant

# Key factors that influence pricing



The landed cost per test for the same/similar products can vary significantly within and across countries. The key factors that determine/influence access to predictable and affordable pricing are as follows:

<b>Global Access Price (GAP) eligibility and access</b>	<b>Limited eligibility or access to GAPs</b> - GAP agreements help to control pricing but are only available for a subset of HPV tests and even where they exist, there can be contractual or policy barriers to accessing them and challenges in executing them
<b>Price inclusivity &amp; transparency</b>	<b>Variable inclusiveness and poor transparency</b> -Unless they are all-inclusive, GAPs and reference prices state a reasonable cost for only a portion of all cost components. Where there are no GAPs, costs can fluctuate and there is no reference for what is fair. This challenge is compounded by the fact that cost components are rarely delineated in meaningful detail for buyers, so it impossible for buyers to evaluate cost drivers and determine what is reasonable.
<b>Procurement &amp; supply chain</b>	<b>Limited and fragmented procurement</b> – For both GAPs and reference prices, the procurement mechanisms and distribution processes adopted by buyers can impact the prices accessed; <i>more predictable, consolidated demand</i> and optimization of volume allocations across suppliers can result in lower costs
<b>Market competitiveness</b>	<b>Limited market competitiveness</b> – Situations of monopolies or duopolies by suppliers and/or distributors for certain market segments or countries contributes to less affordable and consistent prices
<b>Pricing awareness</b>	<b>Limited awareness</b> – Buyers are often not aware of GAPs or other references prices and lack a toolkit of best practices to access affordable and predictable diagnostic prices

<sup>1</sup> Installed base only relevant for PCR platforms

With sufficient HPV test supply, low test demand and uncertainty about HPV test uptake remains a key barrier for large-scale price reduction.

## *Interventions*

1. Support countries with developing **costed screening and treatment plans**, including screening targets.
2. Increase **fundraising efforts** to provide clearer projection of potential funded demand.
3. Increase **transparency of pricing** across suppliers and countries
4. **Country-specific negotiations** have achieved competitive and scalable price offerings. Can be leveraged in specific environments.
5. Introduction of new, affordable solutions such as through **HPV test innovations** and validation of **generic low-cost sample collection swabs and media**



- 1. Total Lab & Supply Chain Costs:** Total instrument and reagent costs include reagents, cartridges, proprietary consumables, controls, instrument, bundled service and maintenance, grant estimates freight and insurance (12%), distributor margin (10%), and logistics/local distribution (2%). Procurement estimates from CHAI UCPOC grant PO analysis in Uganda & Tanzania and HIV VL & EID PO analysis for 2017 procurement in Uganda, Tanzania, Zimbabwe, and Malawi. Customs clearance, taxes, duties, etc. assumed to be waived while supplier trainings assumed included in current pricing. Error rates from Sacks, et al 2021.<sup>1</sup>
- 2. Instrument placement and S&M:** Instrument and bundled service and maintenance costs are assumed covered by HIV/TB programs for multiplexed platforms due to existing device footprint, capacity, and program investments. Cepheid Access Care surcharge assumed covered by TB surcharge, based on structure current country SLA agreements. Additional costs may be incurred for additional instrument placement for multiplex platforms.
- 3. Sample Collection:** Sample collection estimates specified are for supplier-supplied healthcare worker sample collection kit (brush and media), and a combination of ThinPrep PreservCyt Solution (Hologic Inc.) and Rovers Cervex brush for the Cepheid estimates. The Abbott, Hologic and Roche assays are also validated for use with ThinPrep PreservCyt Solution (Hologic Inc.) or SurePath Preservative Fluid (BD).
4. Price per result is \$9.56, while more widely accessible \$11.28 pricing yields a price to result of \$12.00