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## Issue Brief

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# Point-of-Care Early Infant HIV Diagnosis

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## At What Price? Cost Considerations for Integrating Point-Of-Care Early Infant HIV Diagnosis into National Diagnostic Networks

### Introduction

Infants living with HIV that are not initiated on antiretroviral treatment (ART) have high mortality rates.<sup>1</sup> This makes early infant diagnosis (EID), prompt return of results and rapid initiation on ART essential.<sup>2</sup> Virological testing is the only definitive way to confirm HIV status in infants because of the presence of persisting maternal HIV antibody in children up to 18 months of age. The World Health Organization (WHO) recommends virological testing at 4–6 weeks of age for HIV-exposed infants and new guidance also states that birth testing may be considered.<sup>2</sup> Ensuring prompt and adequate EID is still a challenge in many HIV endemic countries. Globally, only half of infants born to HIV-infected mothers undergo EID and of these, only half ever receive their test results.<sup>3</sup>

Recent developments in HIV diagnostic technologies for EID, including point-of-care (POC) nucleic acid testing (NAT) devices that can provide same-day diagnosis in a reliable, rapid manner without a sophisticated laboratory setup, have cultivated hope that POC EID will greatly improve EID and treatment.<sup>4,5</sup>

Elizabeth Glaser Pediatric AIDS Foundation, Médecins Sans Frontières, Clinton Health Access Initiative, and The United Nations Children's Fund, with funding from Unitaid, and its support are working across more than 13 African countries to improve the market for POC EID technologies to make them affordable, sustainable and accessible for all infants who need them. This consortium of purchasers is collaborating with The Global Fund, U.S. President's Emergency Plan for AIDS Relief and other global partners, including manufacturers, to facilitate long-term price reductions in POC EID and increase access to these technologies. The procurement strategy may involve pooling volumes across purchasers with a large proportion of the early POC EID market, providing more advanced forecasts, coordinating orders and jointly negotiating contracts at lower prices and improved service and maintenance terms, while ensuring that there are at least two active manufacturers in the market to encourage the benefits of competition.

It also involves analyzing the cost of goods and improving transparency for pricing, service contracts, and terms and conditions to enable benchmarking and access to competitive pricing and service terms. These organizations are working with The Global Fund to leverage their volumes and harmonize contracts and ensure that The Global Fund grantees will be able to procure these technologies under the same negotiated terms through a most favored customer clause.

## Price transparency

Price transparency is critical to better position countries and implementing partners to access the best prices.<sup>6</sup> Without price transparency, countries and implementing partners face ambiguity in negotiations with manufacturers and distributors for product and service agreements. POC EID price transparency can help ensure access to the best offers for all, thus improving affordability and maximizing patient impact in countries.

## Healthy and sustainable market

A healthy and sustainable market supports competition and empowers countries and implementing partners with negotiation power and less dependency on the conditions established by certain manufacturers. Healthy markets also incentivize current and potential manufacturers to invest in development and commercialization of new or improved tools in a market depending on their observation of current technology saturation. Transparent information on market size can encourage test developers to invest in the development of new POC technology. The resulting competition can contain pricing and facilitate negotiating power for procurers.

## Appropriate service and maintenance fit for context

It is imperative for service and maintenance terms to fit country contexts. To enable developers and manufacturers to create POC EID service and maintenance that fit country contexts WHO, governments worldwide, global health actors and implementers must define a package that reflects context-specific needs and algorithms.<sup>7</sup>

Experience from previous use of POC technologies, such as POC tuberculosis (TB) testing using Cepheid GeneXpert and POC CD4 testing using Alere's Pima, have shown that unless service and maintenance systems are appropriate for resource-limited settings, robust, responsive and cost-effective, many devices will fall non-functional because of unmet service needs or long turn-around time for repairs. Countries also had difficulty providing uniform warranties for the entire fleet with different dates of purchase and different purchasers, complicating appropriate coverage across all machines in a given country.

## POC EID Technologies Pricing and Costing Estimates

A comparison between the advertised prices, total cost of ownership, and cost of goods analysis for POC EID cartridges demonstrates that there is room for price reduction, including through negotiations with manufacturers. A total cost of ownership analysis, conducted by The Global Fund, found that when the price of test kits is combined with apportioned equipment costs and operating costs, such as logistics and servicing and set-up, the total cost of ownership per test ranges from \$22.00- \$42.50 USD.<sup>8</sup> Total cost of goods sold (COGS) includes the cost of the materials used in creating a test kit along with the direct labor costs used to produce it. A COGS analysis prepared by an independent consulting firm in 2016, revealed costs per test kit of \$7.17-\$9.33 USD for Alere Q, and \$9.05-\$10.91 USD for Cepheid. Internal COGS analysis revealed costs 30-40% lower than those above, suggesting there is some room for price reductions in this market, particularly if volumes were to increase or be bundled with similar diagnostics, such as those used to measure POC HIV viral load.

POC technology	Price per test (USD)	Price per machine (USD)	Total cost of ownership** per test kit (USD)	Estimated Cost of Goods sold* per test kit (USD)
Cepheid (GX-XVI) <sup>†</sup>	\$17.95	\$17,000	\$22.00	\$9.05-\$10.91
Alere Q HIV Test <sup>‡</sup>	\$25.00	\$25,000	\$32.50	\$7.17-\$9.33
DRW Samba II	\$37.40	\$26,550	\$42.50	Not Available***

<sup>\*</sup>Range of cost of goods reflects assumption of high and low estimates for costs of intellectual property

<sup>\*\*</sup>Cost of ownership includes test kit, machine, logistics, set up, training, installation, and service costs for the machine, based on 100,000 tests per year

<sup>\*\*\*</sup>Diagnostics for the Real World (DRW) Samba II recently gained stringent regulatory approval, but has not yet been included in the analysis

<sup>†</sup> Communication with Médecins Sans Frontières Access Campaign, May 2016.

<sup>‡</sup> Médecins Sans Frontières Access Campaign. 2013. *How Low Can We Go: Pricing for HIV Viral Load Testing in Low- and Middle-Income Countries*. Geneva, MSF.

## Service and Maintenance Provisions

An analysis of the current service and maintenance provisions of the two current quality-assured systems for POC EID demonstrate there is significant room for improvement to meet plans that are fit for the context of low- and middle-income countries.

Manufacturer	Current provisions
Cepheid GeneXpert IV platform	<ul style="list-style-type: none"> <li>• 24-month limited warranty on service and parts free-of-charge with purchase of a new GeneXpert IV</li> <li>• Warranty covers only failures caused by manufacturing defects and excludes travel costs</li> <li>• Module replacement under 90 days</li> <li>• No real time service and maintenance data available</li> <li>• Extended warranty for \$6,840 USD up-front for additional 3-years or \$2,900 USD yearly offers same conditions as initial warranty. The current extended warranty is more expensive than the purchaser paying to replace each module failure themselves, even if one in every four to five modules failed</li> <li>• Extended warranty includes only shipping costs at carriage and insurance paid to destination (CIP)</li> </ul>
Alere AlereQ platform	<ul style="list-style-type: none"> <li>• 12-month limited warranty with the purchase of a new AlereQ</li> <li>• Warranty does not cover cost of product removal, in-country shipping or reinstallation for the replacement of a failed analyzer covered by the warranty</li> <li>• Extended warranty, with similar conditions to those above, can be purchased for \$2,500 USD per instrument per year. If purchased at the same time as the instrument, the extended warranty is sold for \$9,000 USD covering the same conditions for four years</li> <li>• Few details on Alere's service support model for the AlereQ in sub-Saharan Africa</li> </ul>

## Suggested Areas to Improve Access

### Price reductions

- Costs of goods for cartridges ranged between \$7.17-\$10.91 USD, while market prices are \$17.95-\$25.00 USD
- Manufacturers should consider price reductions for market entry as well as for price-volume breakpoints that fit the size of the EID market

### Provision of more favorable service and maintenance terms

- Replacement of module<sup>5</sup> or device failures free of charge including failures due to operational or environment factors and should cover shipping costs (e.g., at least Incoterm DDP)
- Presence of replacement stock of modules or devices locally or regionally to facilitate prompt on-site module replacement (under 10 working days) from when an in-country distributor is notified
- Local or regional authorized service providers as direct point of contact and support for countries
- Added warranty time to recuperate from device downtimes when the turnaround time is longer than 10 days
- Provision of an online service and maintenance tracking tool to check status of repairs and module/device replacement, and annual module calibration due date (with an alert)
- Extended hours and local contact number (toll free or locally accessible) for technical support
- Free provision of any software and firmware updates

<sup>5</sup> Module failures are defined as modules that are no longer operational and need replacement. From experience, these are modules that fail calibration and need to be sent out for re-calibration, modules which present any mechanical defects (i.e doors not opening or closing) and modules which present an inconclusive results rate  $\geq 5\%$ . Results are defined as inconclusive when the instrument reports an automated result as invalid, error or no result.



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## Pricing Structures

- Manufacturers should consider innovative pricing models to help ensure appropriate coverage for service and maintenance needs, such as including a reasonable increment added to the price per cartridge
- Options for platform leasing or inclusion of platform costs within the price of testing cartridges (i.e. reagent rental), in order to decrease the need for large-up front investments and allow for more predictable budgeting for both implementers and national governments
- Bundling procurement volumes of POC EID with POC diagnostics for other diseases or indications, like tuberculosis or for HIV viral load, can facilitate further price reductions for cartridges and streamline transactional costs<sup>7</sup>
- Volume-based price points should be applied to cumulative global volumes across all members of the global procurement consortium, rather than to individual volumes from a single purchaser

## Conclusions

While the POC EID market is beginning to take shape, more still must be done to improve access to this critical new technology. All key actors – from manufacturers to governments to implementers – must strive to improve price and other key conditions so that HIV-exposed infants and their families globally can see the benefits of timely and accurate HIV diagnosis.

## References

- <sup>1</sup> Violari, Avy, et al. "Early antiretroviral therapy and mortality among HIV-infected infants." *New England Journal of Medicine* 359.21 (2008): 2233-2244.
- <sup>2</sup> WHO. WHO Guidelines 2013. [http://www.who.int/hiv/pub/guidelines/arv2013/download/arv2013\\_chapter05.pdf?ua=1](http://www.who.int/hiv/pub/guidelines/arv2013/download/arv2013_chapter05.pdf?ua=1)
- <sup>3</sup> Cohn, et al. *Improving Market Transparency and Strategic Procurement to Improve Access to POC EID*. 2016.
- <sup>4</sup> UNICEF, CHAI, Unitaid. *Innovation to Save Lives; Project to accelerate access to innovative point of care HIV diagnostics: CD4, early infant diagnosis, and viral load*. 2013. [http://www.unicef.org/aids/files/POC\\_FinalProjectBriefJun2012.pdf](http://www.unicef.org/aids/files/POC_FinalProjectBriefJun2012.pdf).
- <sup>5</sup> Wu G, Zaman MH. Low-cost tools for diagnosing and monitoring HIV infection in low-resource settings. *WHO Bulletin*. 2012;90:914–20. [PMC free article] [PubMed]
- <sup>6</sup> MSF. *How Low Can We Go? Pricing for HIV Viral Load Testing in Low-and Middle Income Countries*. 2013.
- <sup>7</sup> MSF. *Beyond the Microscope: Addressing the critical need for better tuberculosis diagnostics*. 2013.
- <sup>8</sup> The Global Fund. *HIV Viral Load and Early Infant Diagnosis Selection and Procurement Information Tool, Version 2, April 2017*. Accessed on 26 June 2017. Available at [https://www.theglobalfund.org/media/5765/psm\\_viralloadearlyinfantdiagnosis\\_content\\_en.pdf](https://www.theglobalfund.org/media/5765/psm_viralloadearlyinfantdiagnosis_content_en.pdf).

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