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# HIV Early Infant Diagnosis and Viral Load Point of Care Diagnostics: Market and Supply Update

UNICEF Supply Division

March 2020

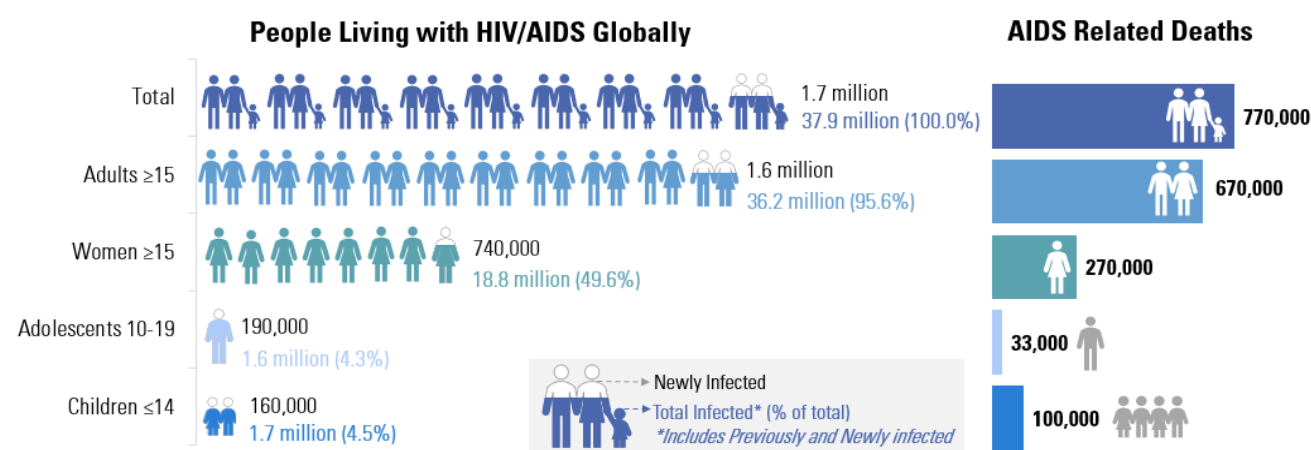
## HIV Early Infant Diagnosis and Viral Load Point of Care Diagnostics Market and Supply Note – March 2020

### 1. Summary

- Currently there are 2.8 million children (up to 18 years of age) that are infected with human immunodeficiency viruses (HIV), making up 7.4 per cent of the global population of people living with HIV (PLHIV).<sup>1</sup> In 2017, only 51 per cent of all HIV-exposed infants were tested for HIV and only 52 per cent of children living with HIV received life-saving antiretroviral therapy (ART).<sup>2</sup> In order to improve HIV testing and treatment coverage, UNICEF procures and supplies point-of-care (POC) tests for HIV early infant diagnosis (EID) and viral load (VL) testing, focusing its support on pregnant women, mothers, infants, children, and adolescents.
- UNICEF's procurement of POC tests for HIV EID and VL testing has grown substantially since 2015 to reach 445,342 tests by 2019, of which approximately sixty per cent were for HIV EID POC tests. UNICEF anticipates procuring between 118,000-168,000 HIV EID and between 72,000-90,000 HIV VL POC tests per year over 2020-2021.
- UNICEF is implementing a strategy to generate demand for HIV EID and VL POC technologies over 2019-2021, while simultaneously calling on HIV EID and VL POC test manufacturers to increase affordability to facilitate growth in demand. The demand for HIV EID and VL POC tests by many low- and middle-income countries (LICs and MICs) is constrained on account of limited domestic resources and dependency on external funding. To support countries to scale up their use of innovative POC technologies for HIV testing, UNICEF approved a three-year catalytic investment for ten countries in West and Central Africa. In addition, UNICEF seeks to mobilize resources and explore opportunities through public-private partnership engagements with product manufacturers.
- The weighted average price (WAP) per HIV EID POC test procured through UNICEF decreased by 19 per cent over 2017 to 2019 from USD 22.93 per test to reach USD 18.62. HIV VL POC WAP per tests on the other hand, increased by seven per cent over the same period from USD 15.19 to USD 16.27. UNICEF continues to encourage HIV EID and VL POC test manufacturers to reach a global ceiling price of USD 15.00 per test across all types of POC tests for HIV EID and VL.
- Currently, there are only two manufacturers with HIV POC diagnostic products prequalified by the World Health Organization (WHO) and eligible for procurement through the United Nations. UNICEF concluded its last tender for HIV EID and VL POC diagnostic technologies in 2018 and awarded two manufacturers long-term arrangements (LTAs) to supply WHO prequalified products. UNICEF's LTAs are open to other United Nations (UN) agencies, funds and programmes to procure and access products under UNICEF's agreed prices, terms, and conditions.

### 2. Background

Figure 1 People Living with HIV/AIDS Globally 2018\*



Source: UNAIDS

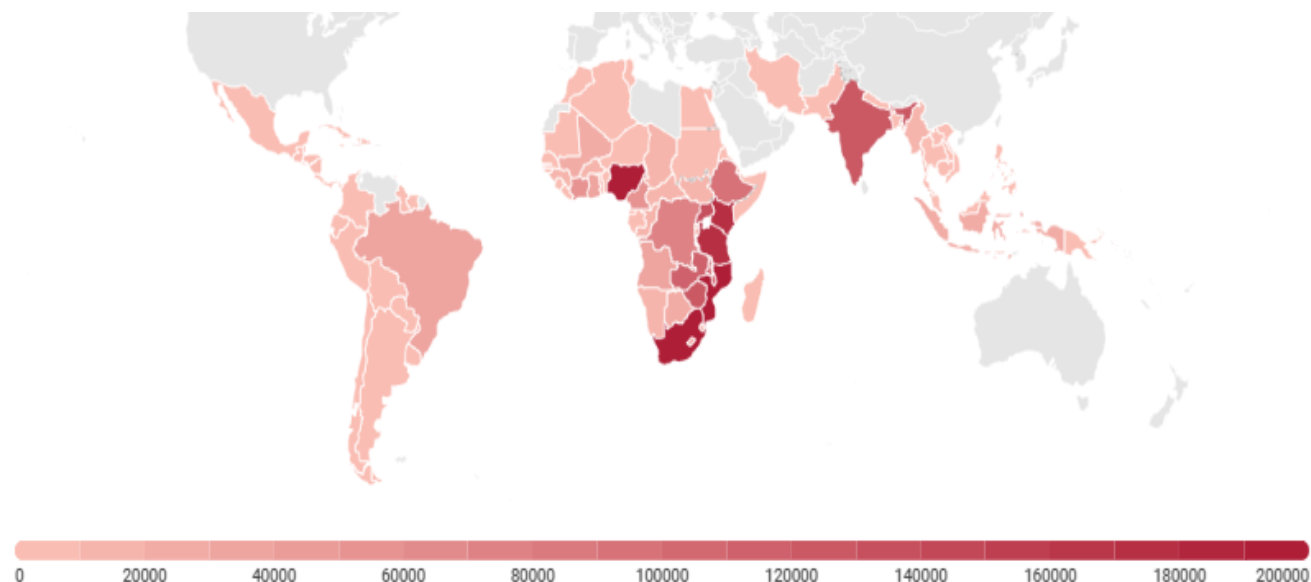
**Note** \*: UNICEF considers the age range of children as 0-18 years of age, representing 2.8 million children, whereas UNAIDS considers the age range of children as 0-14 years of age, representing 1.7 million children (Figure 1).

<sup>1</sup> UNICEF, [HIV Global Regional Trends](#), UNICEF New York, July 2019.

<sup>2</sup> UNICEF, [Expanding Access to Point-of-Care Early Infant Diagnosis: Implementation Approaches and Testing Strategies](#), UNICEF, New York, October 2018, p. 1.

HIV and acquired immunodeficiency syndrome (AIDS) remain a global public health challenge and is responsible for over 35 million deaths since the start of the epidemic in 1981. As of 2018, approximately 37.9 million people were living with HIV/AIDS globally, which increased by approximately 1.7 million new infections from 2017 (Figure 1).<sup>3</sup> Just under seventy per cent of PLHIV are in sub-Saharan Africa (SSA), which is a region that accounts for 91 per cent of all children and 85 per cent of all adolescents living with HIV/AIDS worldwide (Figure 2).<sup>4</sup> Each day in 2018, approximately 980 children became infected with HIV and approximately 320 died from AIDS related causes, mostly because of inadequate access to HIV prevention, care and treatment services.<sup>5</sup>

**Figure 2 Number of Children and Adolescents Aged 19 and Under Living with HIV/AIDS per Region in 2018**

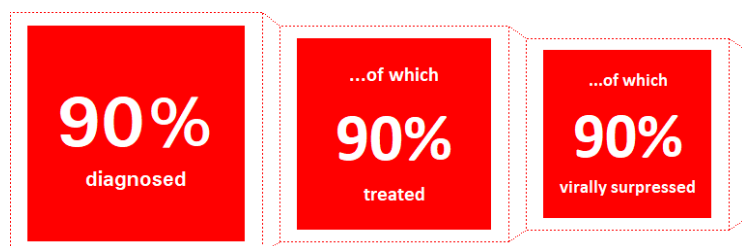


Source: UNICEF

Most children are infected with HIV through their HIV-positive mothers during pregnancy, birth, or through breast-feeding. Whereas early HIV diagnosis and the timely initiation of antiretroviral therapy (ART) could reduce AIDS related child mortality by 76 per cent,<sup>6</sup> a lack of early HIV diagnosis delays access to timely treatment leaving children at a greater risk of mortality. An estimated 30 per cent of HIV-infected infants die during their first year.<sup>7</sup> In 2017, only 51 per cent of all HIV-exposed infants were tested for HIV within the recommended first two months of life, and only 52 per cent of children living with HIV received lifesaving ART.<sup>8</sup>

### 3. UNICEF’s Engagement in HIV and AIDS

**Figure 3 Fast-track Treatment Cascade Global Targets 2020 and 2030**



Source: UNAIDS

In 2014, the world embarked on a fast-track strategy to end the AIDS epidemic by 2030, establishing a target to ensure that by 2020, ninety per cent of PLHIV know their HIV status; of which ninety per cent access treatment; of which ninety per cent suppress their viral loads (90-90-90), and to achieve 95-95-95 by 2030 (Figure 3).<sup>9</sup>

<sup>3</sup> Joint United Nations Programme on HIV/AIDS, [AIDSinfo](#), UNAIDS, Geneva, July 2019.

<sup>4</sup> UNICEF, [HIV and AIDS](#), UNICEF, New York, 2018.

<sup>5</sup> UNICEF, [HIV and AIDS, Global and Regional Trends](#), UNICEF New York, 2019.

<sup>6</sup> Violari, Avy, et al., [Early Antiretroviral Therapy and Mortality among HIV-infected Infants](#), The New England Journal of Medicine, Boston, November 2008.

<sup>7</sup> Unitaid, [Integrating Point-of-care, Early-infant Diagnostics for HIV into National Laboratory Networks](#), Unitaid, Geneva, 2019.

<sup>8</sup> UNICEF, [Expanding Access to Point-of-Care Early Infant Diagnosis: Implementation Approaches and Testing Strategies](#), p. 1.

<sup>9</sup> The Joint United Nations Programme on HIV and AIDS, [Fast track Ending the Epidemic by 2030](#), UNAIDS, Geneva, November 2014.

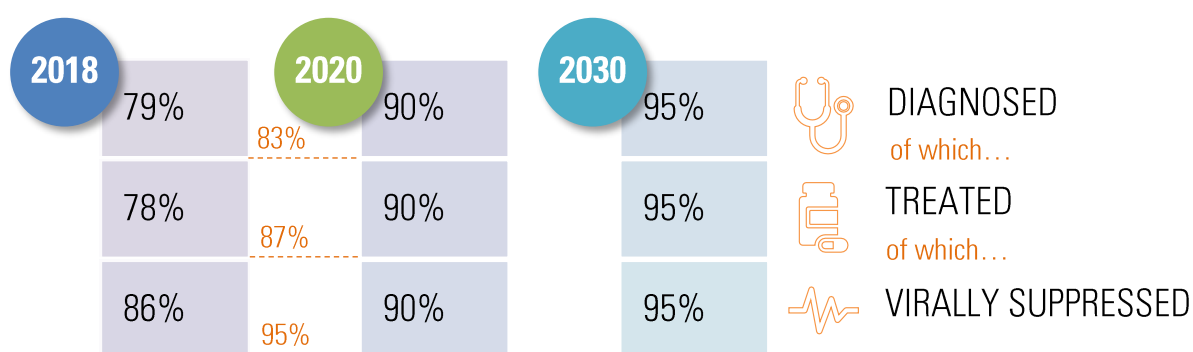


Overall, global progress has been accelerating towards reaching the 90-90-90 target by 2020. At the end of 2018, the world had globally achieved 79-78-86 (Figure 4).<sup>10</sup> South Africa, one of the countries with the world's highest HIV burden, is the closest to meet the 90-90-90 target, with already 85 per cent of its PLHIV knowing their status, of which 71 per cent receive ART, of which 86 percent have suppressed viral loads.<sup>11</sup> However, more effort is needed to achieve the fast track targets for children and mothers.<sup>12</sup> UNICEF seeks to ensure an AIDS-free generation and that **#ForEveryChild**<sup>13</sup> and their families are protected from HIV infection, as well as that children born with HIV do not lose their mothers.<sup>14</sup> To do this UNICEF works to:

- Eliminate mother-to-child HIV transmission through the prevention of mother-to-child transmission (PMTCT).
- Close the HIV treatment gap by reaching more children and adolescents living with HIV with effective treatment.
- Prevent HIV infection in adolescents.

UNICEF engages with partners both at national and global level to make HIV prevention, testing, and treatment as widely available and accessible as possible, including in remote and resource limited settings to reach all children, including in marginalized populations. UNICEF's 2018-2021 strategic plan set a target to ensure that by 2030, 95 per cent of children receive ART to treat HIV infection.<sup>15</sup>

Figure 4 Current Fast-track Treatment Cascade Progress as of end 2018 (see Figure 3)



Source: UNAIDS

As part of this work, UNICEF seeks to sustain market access to HIV products and leverage complementary interventions including those that seek to ensure communities have increased access to, and use of, innovative POC technologies for the EID of HIV and ART monitoring through integrated service delivery.<sup>16</sup> An integrated service delivery in the context of HIV/AIDS promotes the integration of HIV care with reproductive health services; maternal and child health (MCH); sexual transmitted infections (STIs); and non-communicable disease (NCDs).

UNICEF supports governments to strengthen paediatric HIV services with technical assistance and scaling up HIV infant testing through the use of innovative POC technologies. With funding and support from Unitaid, the African Society for Laboratory Medicine (ASLM), an independent pan-African professional organization that coordinates improved local access to quality laboratory services,<sup>17</sup> the Clinton Health Access Initiative (CHAI), and UNICEF work together to accelerate access to HIV POC technologies through national diagnostic programmes in ten focus countries: Cameroon, Democratic Republic of Congo, Ethiopia, Kenya, Malawi, Mozambique, Senegal, the United Republic of Tanzania, Uganda, and Zimbabwe. In 2018, to address the pressing HIV diagnostic and treatment gap in West and Central Africa, UNICEF also approved catalytic investment over three years to introduce and scale up HIV EID POC testing in ten other countries: Burkina Faso, Cape Verde, the Central African Republic, Chad, the Congo, Equatorial Guinea, Gabon, Ghana, Mali, and Nigeria. This project seeks to achieve up to a 25 per cent EID testing coverage in these countries between 2019-2021 to ensure that up to 68,000 HIV-exposed infants are tested in the critical first two months of life.

<sup>10</sup> Joint United Nations Programme on HIV/AIDS, [AIDSinfo: Treatment Cascade](#), UNAIDS, Geneva, July 2019.

<sup>11</sup> Clinton Health Access Initiative, [HIV Market Report: The State of the HIV Treatment, Testing, and Prevention Markets in Low- and Middle-income Countries, 2017-2022](#), CHAI, September 2018, p. 6.

<sup>12</sup> UNICEF, [UNICEF is Working Towards an AIDS-free Generation](#), UNICEF, New York, 2018, p. 5.

<sup>13</sup> Follow UNICEF on Twitter at [#ForEveryChild](#).

<sup>14</sup> UNICEF, [HIV and AIDS](#).

<sup>15</sup> United Nations Economic and Social Council, [Final Results Framework of the UNICEF Strategic Plan, 2018-2021](#), UN, New York, July 2017, p. 16.

<sup>16</sup> The Joint United Nations Programme on HIV and AIDS, [2016-2021 Strategy: On the Fast-track to End AIDS](#), UNAIDS, Geneva, p. 80.

<sup>17</sup> The African Society for Laboratory Medicine, [About ASLM](#), ASLM, Addis Ababa, 2019.

## 4. HIV Early Infant Diagnosis and Viral Load Testing

### 4.1. HIV Early Infant Diagnosis

HIV targets the immune system and weakens the defence systems against infections and some types of cancer. There is currently no curative treatment for HIV infection. However, if diagnosed early and accurately, patients can control their infection by taking ART, which consists of three or more combination antiretroviral (ARV) drugs.

Health care services routinely use HIV rapid diagnostic tests to detect the presence of HIV antibodies to screen and diagnose HIV infection in adults. However, these tests cannot be used to diagnose HIV in infants under 18 months old because of the presence of maternal HIV antibodies. Instead, the early definitive diagnosis of HIV in infants requires the direct virological detection of HIV using molecular technologies such as a nucleic acid amplification test (NAAT) or a nucleic acid test (NAT). WHO recommends that all HIV-exposed infants receive a virological test for HIV within six weeks of birth, followed by the initiation of ART for those who are infected.<sup>18</sup>

### 4.2. Viral Load Testing

The viral load refers to the number of viral particles found in each millilitre of blood. The more HIV viral particles there are in the blood, the faster they are likely to destroy the immune cells and speed the progression of HIV infection towards AIDS.

The purpose of ARV treatment is to reduce the VL to very low or undetectable levels. The monitoring of patients on ART is important to measure and ensure the treatment's efficacy and detect any failure. WHO recommends patients on ART are routinely VL tested at a six- and twelve-month interval after starting treatment and every twelve months thereafter,<sup>19</sup> using molecular technologies such as a NAAT or NAT.

### 4.3. Point of Care Diagnostic Technologies for HIV EID and VL Testing

Up until recently, EID and VL tests needed to be performed in conventional laboratory systems that required significant infrastructure and training. Now both EID and VL testing can be performed outside laboratory settings using innovative POC molecular technologies that have reduced the requirements for infrastructure and training. These technologies allow for tests to be performed in close proximity to where patients are receiving care and can be performed by either professionals or lay health workers delivering the test results relatively quickly.<sup>20</sup> WHO recognizes that POC molecular technologies offer a tangible opportunity to significantly reduce the time it takes health care professionals to diagnose an infant with HIV and initiate treatment that they cannot achieve using conventional EIDs. In its 2016 guidelines for HIV diagnosis in children, WHO recommends the use of POC platforms to diagnose HIV in infants.<sup>21</sup>

POC technologies for HIV EID and VL testing, as they are currently known, are automated or semi-automated systems for molecular testing in a single "sample-in-result-out" process. POC systems are integrated and are typically comprised of an instrument platform, protocol software, and disposable test cartridges. Test cartridges contain all the reagents and internal controls required for the assay in a stabilized form. Each cartridge runs a single test. Samples are applied directly into the cartridges with no further sample processing requirements. The self-contained cartridges are specific to the platform and protocol software.

Existing POC molecular technologies are designed to test for different diseases and conditions using the same polyvalent diagnostic platform. For example, the tests for both HIV EID and VL are integrated onto the same WHO prequalified testing platforms that UNICEF procures. Such integration is considered highly beneficial as it helps improve community access to comprehensive HIV testing. The equipment can be used more optimally with a greater reach, cost-efficiency and effectiveness. Manufacturers of POC molecular technologies are also working to expand the test options to cover other diseases.

UNICEF encourages manufacturers to develop affordable, easy-to-use POC tests for antimicrobial resistance (AMR), as well as for emerging and re-emerging diseases, which highlight the need for prevention, preparedness, as well as effective emergency outbreak response, and which would greatly benefit from POC diagnostics. Diseases affecting

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<sup>19</sup> World Health Organization, [Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection - Recommendations for a public health approach](#), Second edition, WHO, Geneva, June 2016, p. xxxvi.

<sup>20</sup> Unitaid, [Multi-disease Diagnostic Landscape for Integrated Management of HIV, HCV, TB and Other Coinfections](#), Unitaid, Geneva, January 2018, p. 4.

<sup>21</sup> WHO, [Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection - Recommendations for a public health approach](#), p. xxvii.

maternal and child health in addition to tests for non-communicable diseases such as diabetes and cancer could also be considered using existing POC platforms.

Whereas the term “POC” typically refers to diagnostic equipment that can perform a test at the site of care, for example at hospitals, clinics, a doctor’s office, or at home, the term “near-POC” technology is used in addition to “POC” technology to reflect the different inherent features that affect the specific technology’s placement opportunities. In particular, the term “near-POC” typically refers to equipment that does not necessarily perform tests at a patient’s side, but within close range to a site of care. Both POC and near-POC technologies provide rapid test results, enabling health care professionals to make immediate and informed decisions about a patient’s care.

There are a number of companies that have POC and near-POC molecular technologies for HIV EID and VL testing either marketed or in development. UNICEF knows of at least four new technologies that are in early stages of product development, and for which respective manufacturers have not yet set a launch date nor indicative pricing.<sup>22</sup>

As for current marketed POC HIV EID and VL technologies, only two manufacturers have their products prequalified by WHO and eligible for procurement through UNICEF (Table 1). One other manufacturer, Diagnostics for the Real World, submitted an application for WHO prequalification, which, as of March 2020, was still being processed and preparations for a site inspection are in progress.

**Table 1 WHO Prequalified HIV In Vitro POC Molecular Diagnostic Tests**

Manufacturer	WHO Prequalified	Type of Assay	Product Name	Cartridge Pack Size	Shelf-life	Temperature Tolerance	Platform
Alere Technologies (Germany)	2016	HIV / NAT	Alere™ Q HIV-1/2 Detect	10 cartridges / kit 50 cartridges / kit	9 months	4-30°C	m-PIMA™
	2019	HIV / NAT	m-PIMA HIV-1/2 VL	50 cartridges / kit	10.7 months	4-30°C	m-PIMA™
Cepheid (Sweden)	2016	HIV / NAT	Xpert® HIV-1 Qual Assay	10 cartridges / kit	12 months	2-28°C	GeneXpert® System
	2017	HIV / NAT	Xpert® HIV-1 Viral Load	10 cartridges / kit	12 months	2-28°C	GeneXpert® System

Source: World Health Organization

Current WHO prequalified products have a relatively short shelf-life and limited temperature tolerance range, which can present some of the biggest challenges in supply chain management, notably of goods that require international shipping in modest volumes with strict traceability and temperature control, and destined for use in resource limited settings in tropical environments. Efficient supply chain management, storage, handling, and product utilization of short shelf-life goods is of preeminent importance in the field.

UNICEF only procures POC technologies for HIV EID and VL testing that have been prequalified by WHO and that are compliant with UNICEF’s 2016 in vitro diagnostic device (IVD) technical provisions, and its quality assurance policy.<sup>23</sup> <sup>24</sup> WHO’s prequalification programme for IVDs assesses and prequalifies diagnostic products for diseases that pose high individual and public health risks. As of September 2019, WHO has prequalified 55 different HIV IVD’s, accessible here:

[https://www.who.int/diagnostics\\_laboratory/evaluations/PQ\\_list/en/](https://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/)

UNICEF published a technical bulletin ‘[POC and near-POC Diagnostic Technologies for HIV EID and VL Testing](#)’ that provides information on HIV POC diagnostics currently available for procurement through UNICEF to inform and provide guidance to programmes and countries.<sup>25</sup>

National HIV programmes decide what particular EID and VL POC technologies they will choose for their programme in accordance with their national policies, testing guidelines, strategies, and nationally validated testing protocols. Notwithstanding WHO prequalification, UNICEF advises national HIV programmes also implement continuous quality improvement and assurance review processes to identify errors that might lead to misdiagnosis. They should appropriately train their personnel on how to use these technologies and develop and implement quality assurance protocols that are not limited to, but include:

<sup>22</sup> Unitaid, [Multi-disease Diagnostic Landscape for Integrated Management of HIV, HCV, TB and Other Coinfections](#), p. 10-14.

<sup>23</sup> UNICEF, [Technical Requirements for In Vitro Diagnostics \(IVD\)](#), UNICEF, Copenhagen, February 2016.

<sup>24</sup> UNICEF, [Quality Assurance](#), UNICEF, Copenhagen, July 2013.

<sup>25</sup> UNICEF, [Point-of-care \(POC\)/Near POC Virological Technologies for HIV Early Infant Diagnosis \(EID\) and Viral Load \(VL\) Monitoring](#), UNICEF, Copenhagen, September 2019.

- Personnel competence assessment;
- Appropriate documentation of testing activities;
- Lot verification testing for continuous quality improvement;
- Proficiency assessment of testers;
- Performance verification in settings following the national HIV testing guidelines.

UNICEF is undertaking a comprehensive set of actions in support of HIV detection and monitoring, which includes to advocate for the deployment of HIV POC diagnostic technologies for EID and the VL testing of HIV-positive pregnant women and mothers; provide programmatic support to help strengthen and optimize health and laboratory network systems; encourage the integration of disease programmes to avoid funding competition; provide catalytic funding support for the scaling up HIV EID POC in West and Central Africa; support funding and resource mobilization for HIV EID and VL POC technologies; as well as to build public-private partnerships.

The deployment and the uninterrupted use of technology in decentralized and resource limited settings relies heavily on there being an effective and efficient after sales service, with care and maintenance support accessible in these locations. While there has been some progress in the availability of better service and maintenance support from manufacturers of POC HIV EID and VL technologies in many countries over the recent years, further improvements can be made. These could include priority areas such as extending local presence, offering the availability and access to replacement equipment and parts regionally or nationally, as well as possibly equipment upgrades at minimal or no cost. UNICEF and partners are negotiating with the manufacturers the options for improved terms of service and maintenance, while emphasizing their preference for a potential service surcharge with a global ceiling price to be included in a cartridge price.

## 5. Current Market Situation

Market research estimates that the revenues from the global HIV diagnostics market could reach and surpass USD 4.9 billion by 2023, having increased from USD 2.4 billion in 2015, assuming a compound aggregate growth rate (CAGR) of 9.5 per cent.<sup>26</sup> A significant share of this growth will be driven by growing country and private sector HIV infection awareness initiatives, as well as the rising cost from HIV/AIDS on healthcare systems that are increasing the need for HIV diagnostics, and as a result, market size.

LICs and MICs bear the heaviest burden of HIV with seventy per cent of all PLHIV being in SSA and represent the largest potential demand for HIV EID and VL POC diagnostic technologies. They are also critically dependent on external funding sources, which also has an effect on the growth trend in demand. Total funding resources allocated to HIV/AIDS programmes in LICs and MICs from all sources, after having generally been stable averaging approximately USD 18 billion a year, increased from USD 15 billion in 2010 to reach USD 19.9 billion in 2017 and USD 19.0 billion in 2018.<sup>27</sup> However, even though the domestic resources invested by LICs and MICs into their HIV programme responses increased by 50 per cent over this time, while international funding only increased by just 4 per cent over the same period, continued investment is needed to encourage new product introductions and the scaling up of HIV POC diagnostics into national health systems.

### 5.1. HIV Point of Care Early Infant Diagnosis

CHAI estimates that approximately 1.6 million EID tests were undertaken in LICs and MICs in 2018, having increased from 1.4 million EID tests in 2017, with market forecasts estimating that it may surpass 2 million tests by 2020,<sup>28</sup> and could possibly reach 2.2 million by 2022, based on CAGR of 9.46 per cent. CHAI anticipates that the changes in WHO's guidelines will likely drive growth and increase the level of EID testing coverage. This increase is due to the guidelines encouraging testing at birth, using alternative entry point testing, the increasing adoption rate of POC testing, updated WHO algorithms with NAT use at nine months of age, as well as testing at alternative entry points outside of PMTCT settings.<sup>29</sup> As of 2017, less than five per cent of EID testing was performed on POC platforms. However, globally, stakeholders are consolidating their efforts and resources to increase the use of EID POC testing with a target to reach up to 30 per cent of the total HIV EID testing.<sup>30</sup>

<sup>26</sup> Market Watch, [With 9.5% CAGR HIV Diagnostics Market to Bypass USD 4.9 Billion by 2023](#), Market Watch, September 2018.

<sup>27</sup> Joint United Nations Programme on HIV/AIDS, [Communities at the Centre Defending Rights Breaking Barriers. Reaching People with HIV Services](#), UNAIDS, Geneva, December 2019, p. 175.

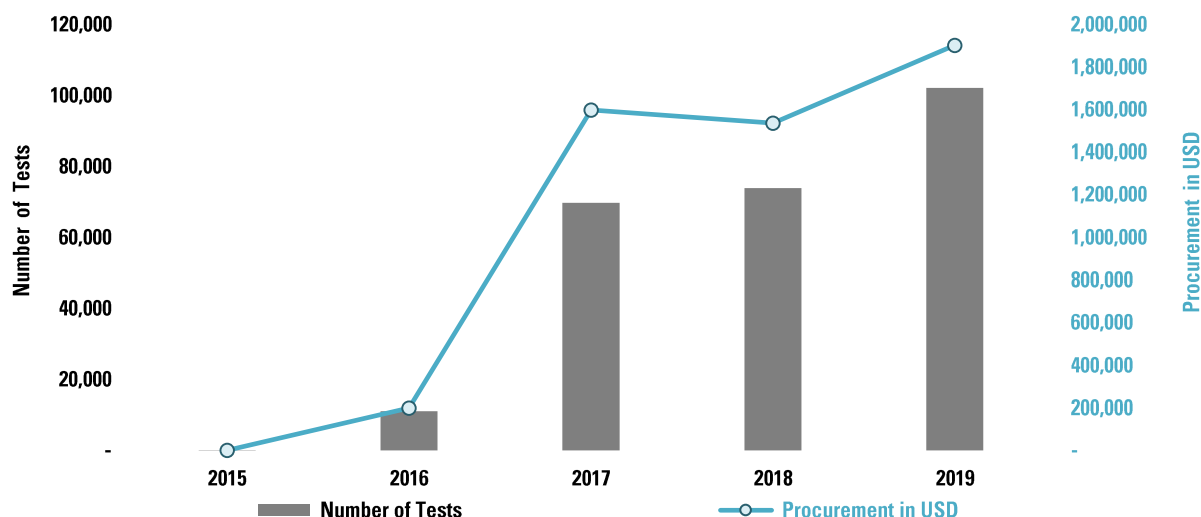
<sup>28</sup> CHAI, [HIV Market Report: The State of the HIV Treatment, Testing, and Prevention Markets in Low- and Middle-income Countries](#), p. 11.

<sup>29</sup> Ibid.

<sup>30</sup> Clinton Health Access Initiative, [POC EID/ VL Procurement Forecast](#), CHAI, Boston, November 2017.

UNICEF started procuring HIV EID POC tests in 2015, with procurement increasing annually to reach over 100,000 tests in 2019. From 2015 to 2019, UNICEF procured over 256,000 HIV EID POC tests totalling USD 5.23 million (Figure 5). In 2018, UNICEF procured 73,800 tests, which even though represented only 4.7 per cent of the overall total volume of EID tests in LICs and MICs, UNICEF still currently represents the single largest source of HIV EID POC test procurement. In 2019, UNICEF procured 102,110 tests representing an increase of 38 per cent. More than ninety per cent of UNICEF HIV EID POC procurement over the past four years (2016-2019) was for countries supported by Unitaid.<sup>31</sup> In addition, UNICEF procured HIV EID POC tests on behalf of 14 other country programmes, of which all but two (Fiji and Solomon Islands) are in SSA, which has steadily increased to reach 6.7 per cent of its current overall HIV EID POC test procurement volume. UNICEF anticipates this trend in growth to continue as the demand from UNICEF supported country programmes for HIV EID POC technologies continues.

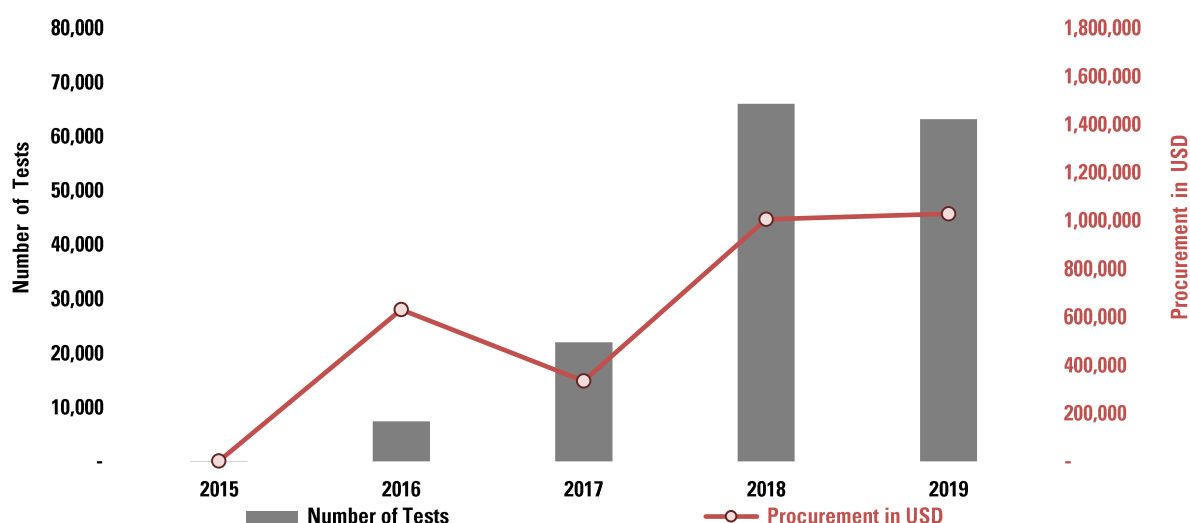
Figure 5 UNICEF HIV EID POC Test Procurement and USD Value 2015-2019



Source: UNICEF Supply Division

## 5.2. HIV Point of Care Viral Load Tests

Figure 6 UNICEF HIV VL POC Test Procurement and USD Value 2015-2019



Source: UNICEF Supply Division

<sup>31</sup> Unitaid, [Accelerating Access and Integration to Innovative Point-of-Care Diagnostics for HIV in National Diagnostic Programmes](#), Unitaid, Geneva, 2019.



UNICEF has procured more than 188,000 HIV VL POC tests since 2015 totalling just below USD 3 million (Figure 6, preceding page), with annual procurement reaching 63,190 tests in 2019. UNICEF has mostly procured HIV VL POC since 2016 on behalf of countries supported by Unitaid,<sup>32</sup> in addition to supporting UNICEF country programmes in Fiji, Niger, Solomon Islands, and Somalia, representing up approximately 17 per cent of the volume.

Similar to EID testing, countries are scaling up their use of VL testing. CHAI estimates that LIC and MIC countries carried out over 14 million VL tests in 2017,<sup>33</sup> and 18 million tests in 2018.<sup>34</sup> It estimates that the number of VL tests carried out in LICs and MICs could double to reach approximately 31 million tests by 2023, based on a CAGR of 14 per cent.<sup>35</sup> WHO's recommendation to use VL testing to monitor ART treatment in addition to the availability of funding could drive the growth in demand for VL tests. Globally, stakeholders are working to secure between 10 per cent to 36 per cent market share for VL POC technologies,<sup>36</sup> since wider use of POC technologies is seen to critically enable increased VL testing coverage and improvements in treatment outcomes. However, as of 2018, less than one per cent of VL testing was performed using POC technology.<sup>37</sup>

HIV EID and VL POC manufacturers do not retain significant inventories of finished product and it can take seven to eight weeks lead-delivery time to supply finished products to UNICEF. UNICEF awarded both manufacturers with WHO prequalified HIV POC NAT diagnostic products multi-year (three plus one) LTAs following its last tender concluded in September 2018, and which can be used by other United Nations agencies to procure. UNICEF does not consider the production capacity of either manufacturer as limiting demand, nor likely to become a constraint in the short- to medium-term. However, the limited local presence of HIV EID and VL POC manufacturers in SSA limits opportunities to improve and enhance service delivery. If manufacturers established presences in countries or regions, including through authorized representatives or dealerships, they could offer an opportunity to explore options for improved service delivery to address issues including critical elements such as, but not limited to, remote and on-site equipment diagnostics, delivery, installation, commissioning, and trainings, as well as after sales services such as maintenance, repairs, provision of consumable supplies, product replacements, as well as the removal and proper waste disposal of old obsolete equipment. Not only could this approach help contribute to total life cycle product management, local economic development, but also promote sustainable procurement.



### Sustainable Procurement

In February 2018, UNICEF released its Procedure on sustainable procurement (SP) ([SUPPLY/PROCEDURE/2018/001](#)). The procedure constitutes UNICEF's policy on SP and is applicable across all UNICEF offices engaged in supply planning and procurement, wherever feasible and applicable, whether for goods or services, or for programmes or office assets. You can read more [here](#).<sup>38</sup>

Sustainable procurement is an approach to procurement that incorporates the three sustainability pillars of social, economic, and environmental impact considerations. It goes beyond the more familiar "green" public procurement, to ensure that all products and services procured support local economic and social development, with the least environmental impact, and the best value for money (VfM).

In implementing SP, UNICEF seeks to include green manufacturing quality management systems, and social and economic considerations as SP criteria in commercial tender evaluations, as well as specific supply targets to develop local industry capacity in programme countries.

In applying SP, many UNICEF procurement decisions will face trade-offs between SP's three pillars (economic, social, and environmental), and present key operational challenges, especially between environmental and social considerations, with the latter often being more difficult to quantify. The absence of evidence to make any informed trade-off decisions will be part of the

<sup>32</sup> Ibid.

<sup>33</sup> Clinton Health Access Initiative, [HIV Market Report: The State of the HIV Treatment, Testing, and Prevention Markets in Low- and Middle-income Countries, 2017-2022](#), CHAI, September 2018, p. 17.

<sup>34</sup> CHAI, [HIV Market Report: The State of the HIV Treatment, Testing, and Prevention Markets in Low- and Middle-income Countries](#), p. 22.

<sup>35</sup> Ibid.

<sup>36</sup> Unitaid, [Market and Product Landscape Update](#), Unitaid, Geneva, November 2017.

<sup>37</sup> Clinton Health Access Initiative, [POC EID/VL Procurement Forecast](#), CHAI, Boston, November 2017.

<sup>38</sup> UNICEF, [Sustainable Procurement](#), UNICEF, Copenhagen, September 2018.

challenge. The other challenge will be the difficulty to make value judgments to prioritize one pillar over the other. However, solutions will be situation specific and priorities based on readiness, market influence, and targeted objectives.

Some SP elements, notably under the social pillar, may put some pressure on short-term costs that generate longer-term savings, such as investments in fairer employment working conditions, or health and safety, which would be offset by increased motivation, productivity, and reductions in work-related injury and absenteeism. To achieve higher tangible economic benefits and VfM, UNICEF and industry will strive to manage procurement decisions based on longer-term perspectives, considering the advantages of environmentally, socially sound products and services, and better performing staff, bring in the long-term.

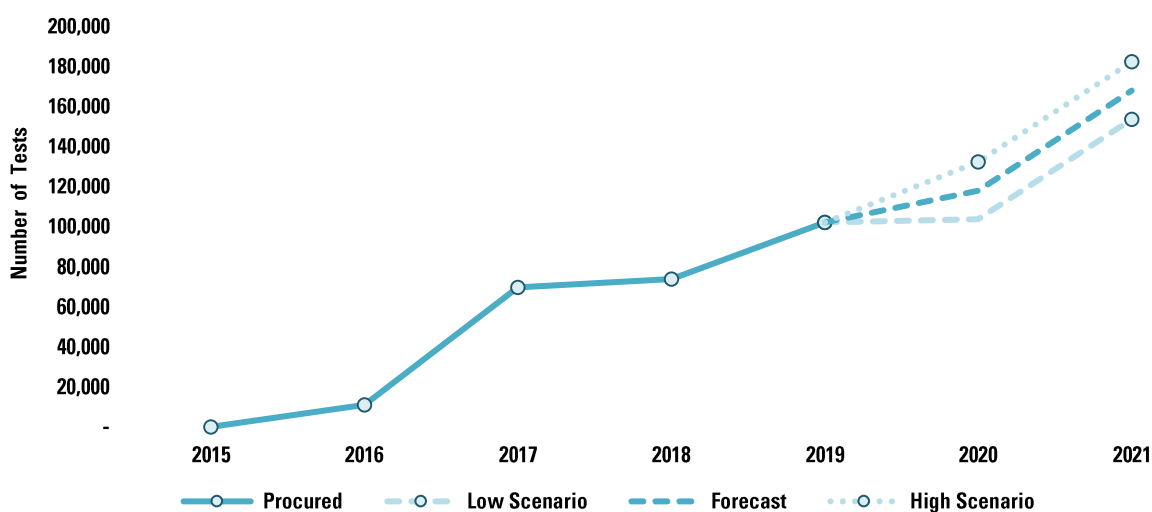
Source: UNICEF Supply Division

### 5.3. Demand through UNICEF

UNICEF’s demand forecast for HIV EID and VL POC tests through 2020 and 2021 (Figure 7) is based on its historical procurement analysis and ongoing developments in its two major projects driving HIV EID and VL POC demand, which are its UNICEF-funded project “HIV EID POC Scale Up in West and Central Africa” designed for 2019-2021; and its Unitaid-funded project “Accelerating Access and Integration to Innovative POC Diagnostics for HIV in National Diagnostic Programmes” rolling since 2016 through 2020.

UNICEF anticipates that the demand for HIV EID POC tests will continue to increase with continued funding support. It currently envisages the demand for HIV EID POC in 2020 will increase moderately, to reach approximately 118,000 tests, considering that Unitaid’s project, main driver of demand, is coming to an end; and the other major project in Central and West Africa is still at a very early stage of implementation. However, in 2021, UNICEF anticipates a much higher demand, which could possibly reach up to 168,000 tests, based on its assessment that many countries may have sufficiently scaled up their HIV EID POC testing programmes; and that UNICEF has accelerated the adoption of HIV EID and VL POC technologies in West and Central Africa.

Figure 7 UNICEF HIV EID POC Test Demand Forecast 2020-2021

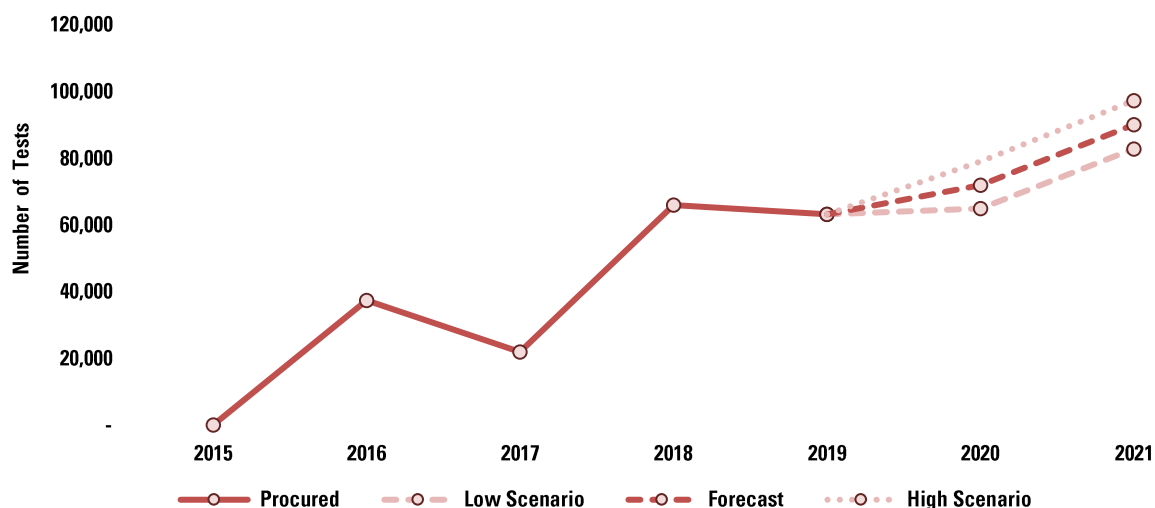


Source: Supply Division

Similar to HIV EID POC, UNICEF’s HIV VL POC test demand forecast envisages its procurement to continue to increase and generally follow an upward trend over the next few years, despite a four per cent drop in 2019, due to the transition of the HIV VL POC testing procurement support within the framework of the Unitaid-project (Figure 8, next page). In 2020, UNICEF anticipates its procurement forecast to reach 72,000 tests to sustain scaling-up in West and Central Africa, and to possibly reach up to over 90,000 tests by 2021 on condition UNICEF successfully implements its 2019-2021 HIV EID and VL POC demand generation strategy, and many countries may have sufficiently scaled up their HIV EID POC testing programmes.

In order to obtain more accurate assessments of HIV EID and VL POC diagnostic procurement forecasts from those countries not covered by one of UNICEF’s two key projects driving demand, UNICEF included the demand for HIV EID POC tests in its 2019 immunization health products forecast, which is UNICEF’s annual global forecasting exercise covering most of the critical commodities it procures on behalf of countries.

Figure 8 UNICEF HIV VL POC Demand Forecast 2020-2021



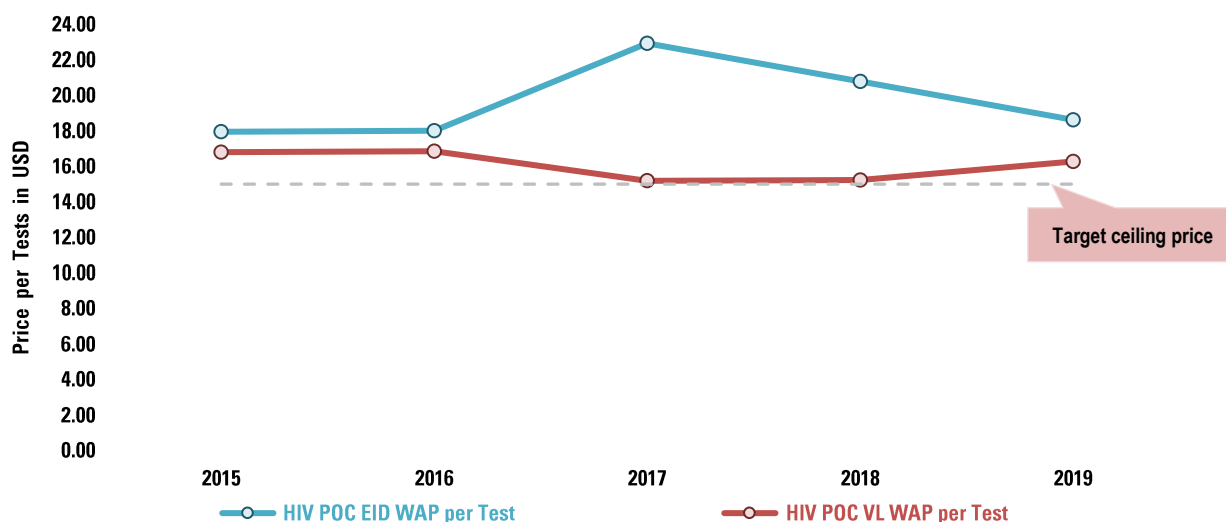
Source: UNICEF Supply Division

#### 5.4. Prices

UNICEF publishes detailed information on all its products in its [UNICEF Supply Catalogue](#), and which includes indicative price information for the HIV EID and VL POC testing technologies available for UNICEF programmes and procurement partners.

From 2015 to 2018, the weighted average price (WAP) per HIV EID POC test through UNICEF procurement increased by 16 per cent from USD 17.95 to reach USD 22.93 in 2017 based on free carrier incoterms (FCA). However, UNICEF was able to secure a price reduction with one of its manufacturers for initially ten early-adopting countries and later extended it to all LICs and MICs, which reduced the WAP for HIV EID POC tests by almost nineteen per cent per test over 2017-2019 (Figure 9). On the other hand, UNICEF's WAP per HIV VL POC test increased by seven per cent over the same period, from USD 15.19 in 2017 to USD 16.27 in 2019. The increase was due to the market launch and introduction to UNICEF procurement of a comparatively more expensive new POC HIV VL test that received WHO prequalification in 2019.

Figure 9 UNICEF HIV EID and VL POC Weighted Average Price 2015-2019



Source UNICEF Supply Division

There currently exists a sizeable price difference between the POC tests currently available on the market and conventional EID and VL tests, which suggests there are opportunities for price improvements. Even though POC tests are not intended to replace conventional tests, as they are complementary and are used under different conditions and

circumstances, UNICEF encourages HIV EID and VL POC manufacturers to lower pricing with a global target to achieve a price ceiling USD 15.00 per test across all types of molecular POC tests for HIV EID and VL.

UNICEF is currently exploring innovative all-inclusive pricing arrangements that have the potential to transform the way diagnostic technologies are procured by addressing a number of common challenges through market interventions. These include the reduction in machine downtime, minimizing stock-outs and wastage, improving the placement of devices for more efficient use, making pricing more transparent, and reducing the costs to switch products for national programmes and donors. In an all-inclusive pricing arrangement, a single price typically includes instrument placement, delivery, installation and commissioning, a comprehensive care and maintenance package with service terms, as well as reagents, and consumables, to be delivered to the laboratories; other elements may be included optimally.

UNICEF and CHAI are currently implementing a pilot project to explore all-inclusive contract modality for conventional molecular diagnostics in four country under Unitaid funding. This initiative will provide key information on the pathway and challenges faced when shifting to locally monitored contracts and will help moving supply terms along the continuum of options towards eventual adoption of all-inclusive pricing arrangements across all lab-based and POC technologies.

## 6. Issues and Challenges

There are a number of issues and challenges that could affect countries and their ability to scale up their use of HIV EID and VL POC diagnostic technologies:

- **Disease integration:** As interest in EID and VL POC increases, many countries will have to decide on how to accommodate the demand for new POC testing platforms, as well as to determine the feasibility and acceptability of integrated disease testing using polyvalent capacities of such platforms to increase equipment utilization rates and achieve higher cost-efficiencies for disease testing.
- **Product availability:** The current choice of WHO prequalified POC diagnostic technologies for HIV EID and VL testing eligible for UNICEF procurement is limited to two products from two manufacturers, of which one is a near-POC instrument. UNICEF anticipates several new products and potential suppliers in the pipeline but has no visibility on when they could become available.
- **Quality assurance:** Countries have different regulatory pathways that do not always lend themselves to the quick introduction and use of new diagnostics technologies. Lacking guidance on integrated testing service introduction using innovative polyvalent POC platforms raises concerns on how to sustain testing quality. There is also a challenge in how to introduce and maintain the uniform quality control processes and tools for molecular testing at the lower tier levels of the health care system.
- **Affordability:** Currently the pricing for HIV EID and VL POC tests are higher compared to conventional tests, as well as there being a sizable price gap between existing available POC technologies.
- **Sustainable demand:** WHO recommendations for HIV testing are regularly updated, which affects demand, making it difficult for manufacturers to keep up with appropriate development technology, while also securing a sufficient return on investments combined with the need for continued product development. The competition between the different POC and conventional testing platforms also makes it difficult to ensure that manufacturers secure a viable share of the market, which also limits their visibility on any medium or long-term demand, which does not provide manufacturers with sufficient incentive to lower pricing.
- Countries have strong product and manufacturer preferences, which makes it difficult for new market entrants with new technology to secure sustainable demand. The current HIV EID and VL POC market size and procurement volumes are still in its initial phases of development and not yet sustainable.
- **Supply:** Existing tests for EID and VL POC have a limited shelf-life and temperature tolerance range, which puts greater demands and pressure on inventories and stock management. Manufacturers also have a limited established presence in countries or regions, including through authorized representatives or dealerships, preventing them from developing any options that could offer improved service delivery to address issues such as including on-site equipment delivery, installation, trainings, as well as after sales maintenance, repairs, provision of consumable supplies, product replacement, as well as the removal and proper waste disposal of old obsolete equipment.
- **Data privacy:** The issue of patient data confidentiality, ownership, privacy, and storage responsibility is uncertain, as well as access to test results and the exchange of data within the continuum of care. The use of any data capturing technology and the ownership of that data needs to be critically assessed through an ethical lens prior to engaging in any partnership or implementing any programmes or analysis. As the protection of personal data relates



to the rights to privacy recognized in human rights instruments.<sup>39</sup> The United Nations High-Level Committee on Management (UN HLCM) published in 2018 the principles governing personal data protection and privacy.<sup>40</sup> It sets out the basic framework for processing the personal data of an identifiable person by any organization carrying out mandated activities on behalf of the United Nations System. UNICEF also published a discussion paper on “*Children’s Right and Business in a Digital World*”, which discusses the issue of privacy, data protection of personal information, and reputation rights.<sup>41</sup>

- **Funding:** LICs and MICs concentrate domestic funding on essential health care and universal health coverage but persistently rely on external sources of funding to scale up innovations.

## 7. Steps Forward

- UNICEF will continue to support and promote increased access to HIV EID and VL testing and improved testing services in primary health care facilities through scaling up the use of POC technologies within integrated laboratory networks to extend reach.
- UNICEF will continue to support optimizing laboratory networks and promote regional and national initiatives integrating innovative disease diagnoses by encouraging the use of polyvalent molecular POC platforms.
- UNICEF will continue to implement its HIV EID and VL POC demand generation strategy to guide its 2020-2021 engagement.
- UNICEF will continue to engage in its broad strategic partnerships to mobilize funding resources in support of developing and scaling up the use of POC diagnostic technologies for HIV EID and VL testing to encourage HIV EID and VL POC markets to lower pricing with a target to achieve a price ceiling of USD 15.00 a test across all types of molecular POC tests for HIV EID and VL.
- UNICEF will also continue to review its supply terms for molecular POC diagnostics, including for HIV, and explore what innovative all-inclusive pricing arrangements it can devise.
- UNICEF encourages manufacturers of POC diagnostic technologies for EID and VL testing to improve product service and maintenance terms; as well as to establish regional service hubs and training centres in Africa, as well as explore opportunities to establish local production capacities for innovative POC diagnostics.
- UNICEF will follow developments in product innovation and will carefully review all new molecular POC technologies for HIV EID and VL testing that arrive on the market.

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Other UNICEF information notes are found at [http://www.unicef.org/supply/index\\_54214.html](http://www.unicef.org/supply/index_54214.html).

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<sup>39</sup> There are many different international texts that serve as sources for international human rights law. The Office of the United Nations High Commissioner for Human Rights (OHCHR) identifies nine core international human rights instruments see [here](#), which includes the [Convention on the Rights of the Child](#) (CRC, 20 November 1989), which is the basis of all of UNICEF’s work.

<sup>40</sup> United Nations High-level Committee on Management, [Personal Data Protection and Privacy Principles](#), UN, New York, October 2018.

<sup>41</sup> UNICEF, [Children’s Rights and Business in a Digital World: Privacy, Protection of Personal Information and Reputation Rights](#), UNICEF, New York.