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MARKET AND TECHNOLOGY LANDSCAPE

HIV RAPID DIAGNOSTIC TESTS FOR SELF-TESTING

4th EDITION

JULY 2018

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Contents

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Abbreviations

AIDS	acquired immunodeficiency syndrome
CE	Conformité Européenne
CIFF	Children's Investment Fund Foundation
ERPD	Expert Review Panel for Diagnostics
FDA	Food and Drug Administration
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
GHSC	Global Health Supply Chain
GHTF	Global Harmonization Task Force
HIC	high-income country
HIV	human immunodeficiency virus
HIVST	HIV self-testing
IFU	instructions for use
IMDRF	International Medical Device Regulators Forum
IVD	in-vitro diagnostic device
ISO	International Organization for Standardization
LMIC	low- and middle-income countries
MSF	Médecins Sans Frontières
NGO	nongovernmental organization
PAAR	prioritized above allocation request
PEPFAR	President's Emergency Program For AIDS Relief
PLHIV	people living with HIV
PQ	prequalification
PrEP	pre-exposure prophylaxis
RDT	rapid diagnostic test
STI	sexually transmitted infection
STAR	Self-Testing Africa (Initiative)
USAID	United States Agency for International Development
WHO	World Health Organization

Executive Summary

People's knowledge of their and their partners' HIV status is essential to the HIV response. It is the first step to both prevention and treatment, which reduce HIV-associated morbidity, mortality and transmission. Many people continue to miss out on these benefits, however. In 2017 an estimated 9.4 million people – 25% of all people living with HIV – were unaware of their HIV-positive status. While testing coverage has increased substantially, many of those who remain unreached are men, young people (ages 15–24) and members of key populations – men who have sex with men, people in prisons and other closed settings, people who inject drugs, sex workers and transgender people.

HIV self-testing has emerged as an acceptable, safe, accurate and effective way to reach people who are at risk and may not otherwise test. In 2016, WHO recommended HIV self-testing to be offered as an additional approach to complement existing HIV testing services. Following these guidelines, 59 countries now have policies supporting HIV self-testing. Some 53 other countries report they are developing policies on HIV self-testing, many of which are expected to be completed in 2018. Despite rapid uptake of the policy, implementation of HIV self-testing remains limited to 28 countries, which is a considerable increase from 13 in July 2017. About two-thirds (n=18) of the countries implementing HIV self-testing are upper middle- or high-income countries.

The HIV self-testing procurement forecast suggests significant growth in the market for HIV self-tests in both public and private sectors up to and beyond 2020.

The procurement forecast suggests significant growth in the market for HIV self-tests in both public and private sectors up to and beyond 2020. The global self-test volumes are expected to grow from 1 million tests in 2017 to an estimated 16.4 million (12.9 million – 19.3 million) by the end of 2020. The public sector is expected to contribute 9.1 million (6.3 million – 11.2 million), while the private sector is expected to account for the remaining 7.3 million (6.6 million – 8.0 million) self-tests. In the public sector, initial growth is driven predominantly by confirmed procurements by donors including Unitaid and the United States President's Emergency Plan For AIDS Relief (PEPFAR) in five key countries – Kenya, Malawi, South Africa, Zambia and Zimbabwe. However, from 2019 onwards, the market is expected to grow further and to diversify as additional countries

implement and scale-up HIV self-testing. It is expected that in 2020, low- and middle-income countries (LMICs) other than the five key countries will procure 46% of all self-tests. In the private sector the forecast reflects continued and steady growth in HIV self-test volumes in the three early-adopting high-income countries (France, the United Kingdom and the United States of America). Beyond 2019 additional upper-middle income countries are expected to drive the growth of private sector HIV self-test volumes.

As of July 2018, eight HIV self-tests (two oral fluid tests and six blood-based tests) have either been prequalified by WHO, approved by a stringent regulatory authority in one of the founding members of the International Medical Device Regulators Forum,[1] or recommended for procurement by the Unitaid/Global Fund Expert Review Panel for Diagnostics.[2] Only one HIV self-test, an oral fluid test, has been prequalified by WHO. Additional locally manufactured HIV self-tests with national-level approval have emerged in some countries (six products identified), including Belarus, Brazil and Nigeria. The quality and performance of these products are largely unknown. There are at least six other HIV self-tests under development. Three of these self-tests use whole blood specimens, two use oral fluid specimens, and one uses urine specimens.

The price of HIV self-tests with WHO prequalification or stringent regulatory approval varies considerably, depending on the setting, market sector and product packaging format (some products are sold in different packaging formats in different markets). In high-income countries prices in the private sector range from US$ 20 to US$ 48 per test, while the prices for public sector or nongovernmental organization procurement range from US$ 7.5 to US$ 15 per test. In LMICs self-tests are available at a lower price, ranging from US$ 2 to US$ 12 per test in the public sector and US$ 7 to US$ 12 per test in the private sector. The lowest price per test, US$ 2, is available in the public sector in 50 high HIV burden LMIC settings for a limited time through an agreement between the Bill & Melinda Gates Foundation and the manufacturer of the only WHO-prequalified self-test.

The market for HIV self-tests continues to evolve rapidly, supported by the release of WHO guidelines and clear prequalification processes, the WHO prequalification of one self-test, and increased donor investment and price reductions in public sector LMIC settings. The growing uptake of HIV self-testing policy and implementation is encouraging. In several high HIV burden countries, self-test kits are forecast to account for a small proportion of total rapid diagnostic test volumes. This

[1] The founding members of the International Medical Device Regulators Forum (IMDRF) are Australia, Canada, the European Union, Japan and the United States of America. The IMDFR was previously known as the Global Harmonization Task Force (GHTF). More information is available at http://www.imdrf.org/ghtf/ghtf-archives.asp.
[2] More information can be found at https://www.theglobalfund.org/en/sourcing-management/updates/2017-07-12-hiv-self-testing-kits-assessed-for-eligibility for-procurement-by-the- expert-review-panel/

observation suggests opportunities for the growth of HIV self-testing. Further market growth opportunities are expected to emerge as the application of self-testing and self-sampling technologies expands to other relevant disease areas and innovations in product design and manufacturing processes develop.

The market for HIV self-tests continues to evolve rapidly, but barriers remain.

Despite substantial progress, barriers to HIV self-testing implementation and scale-up remain. Consumer choices and market competition is largely limited due to only one WHO prequalified self-test, which dominates the donor-funded market. Lack of clarity or the absence of national regulatory pathways in some settings is hindering market entry for new products, thereby delaying wider implementation and scale-up.

To achieve the full potential of HIV self-testing and to maximize its public health impact, all stakeholders need to play a role. This report recommends six priority areas for action by all stakeholders:

- WHO prequalification of additional products to diversify the available range and specimen type for donor-funded programmes, supported by streamlining of national regulatory, registration and product selection processes;
- adapt and develop national-level investment cases to demonstrate public health benefit and inform implementation;
- implement and harmonize strategies that achieve a sustainable market and make self-testing affordable to consumers (individual users, governments and donors);
- increase awareness and demand for HIV self-testing through health promotion and implementation of innovative service delivery models across public and private sectors;
- establish and leverage strategic partnerships between manufacturers and local distributors to reduce manufacturers' risk and to facilitate entry into new and emerging markets; and
- continue product optimization and innovation, along with efforts to expand the use and adaptation of self-testing products for other relevant disease areas and establish a broader market for self-testing.

Background

Global targets and the scale-up of HIV testing services

Learning one's HIV status through HIV testing is the gateway to prevention and treatment services, which are highly effective in reducing HIV-associated morbidity and mortality *(1, 2)* and can prevent onward transmission of HIV *(3–7)*. HIV testing services are also key to achieving the United Nations 90–90–90 targets by 2020, which start with diagnosing 90% of people living with HIV *(8)*. To date, the global scale-up of HIV testing services has been substantial. Between 2010 and 2014, more than 600 million people received HIV testing services in 122 low- and middle-income countries (LMICs) *(9)*. In 2017 alone, more than 122 million HIV tests were procured by major donors *(10)*. In 2017 approximately 75% of people living with HIV were aware of their HIV status, an increase from 67% in 2015 *(11)*. Recent population-based surveys in several countries also reflect this expansion, showing overall increases in knowledge of HIV status *(12)*.

Despite substantial scale-up of HIV testing, 25% of people living with HIV remain undiagnosed.

Despite substantial scale-up of HIV testing, as of 2017 an estimated 9.4 million people – 25% of all people living with HIV – were unaware of their HIV-positive status *(11)*. In many settings many of the tests performed do not necessarily reach people at increased risk of HIV or people with HIV who are unaware of their status *(13)*. Testing coverage remains low in key populations[1] *(9, 14)*, which account for nearly half of new HIV infections each year globally *(11)*. Testing rates also continue to be low among men, adolescents and young people *(9, 15)*. The gap in HIV testing is also reflected in high rates of advanced disease at treatment initiation (CD4+ T-cell count under 200 cells/mm3) in many countries *(12)*, which is associated with worse health outcomes *(1, 2)*. For example, data from 85 countries show that nearly one third (29%) of all people with HIV had advanced disease at the time of diagnosis and approaching half (41%) in Asia and the Pacific *(12)*.

[1] The WHO defines key populations as groups who, due to specific higher-risk behaviours and barriers that increase their vulnerability, are at an increased risk of HIV irrespective of the epidemic type or local context and often have legal and social issues related to their behaviours that increase their vulnerability to HIV. Key populations include men who have sex with men, people in prisons and other closed settings, people who inject drugs, sex workers and transgender people.

HIV self-testing: an innovation to close the gap in testing

In 2016, the World Health Organization (WHO) recommended HIV self-testing as an additional approach to complement existing HIV testing services (Box 1). HIV self-testing has emerged as an acceptable, safe, accurate and effective way to reach those who may not otherwise test *(16–18)* (Box 2). The latest evidence suggests that, when focused towards high-risk groups and those with low testing coverage, HIV self-testing can be cost-effective and achieve public health impact *(19, 20)*.

This report presents the latest (July 2018) global HIV self-testing market forecast and gives an overview of HIV rapid diagnostic tests for self-testing currently available or under development. The intended audiences for this report include manufacturers of diagnostic tests, donors and funders, national programme managers, national regulatory authorities, researchers and other global health stakeholders involved in implementing and scaling up HIV self-testing.

Box 1. HIV SELF-TESTING

What is HIV self-testing?

HIV self-testing refers to a process in which a person collects his or her own specimen (oral fluid or blood) and then performs an HIV test and interprets the result, often in a private setting, either alone or with someone he or she trusts. As with all approaches to HIV testing, HIV self-testing should always be voluntary, not coercive or mandatory.

An HIV self-test does not provide a definitive HIV-positive diagnosis.

*An HIV self-test is a "test for triage", which requires individuals with a **reactive** test result to receive further testing from a trained tester using a validated national testing strategy. In addition, all users with a **non-reactive** self-test result should be advised to retest if there is a possibility that they were exposed to HIV in the preceding 6 to 12 weeks or if they are at high ongoing HIV risk. Any person who is **uncertain** about how to correctly perform the self-test or interpret the self-test result should be provided with contact details and information about HIV testing services and encouraged to obtain facility-based or community-based HIV testing services.*

Source: WHO, 2016 *(21)*

Box 2. HIV SELF-TESTING CAN ENGAGE HIGH-RISK AND HARD-TO-REACH PEOPLE IN TESTING: EXPERIENCE IN THE RUSSIAN FEDERATION

In the context of stigma and discrimination experienced by men who have sex with men and transgender people in Russia, providing convenient, discreet and anonymous testing and referral options is important.

The Safe Box project, supported by the Elton John AIDS Foundation, began in 2017 in five large cities – Moscow, Omsk, Orel, St. Petersburg and Yekaterinburg. It gives men who have sex with men and transgender people access to free HIV self-test kits at community organizations, clinics, private pharmacies, clubs and saunas as well as via mail and from volunteers. When gay dating apps, social media and gay friendly websites promoted the service, project coverage increased by about 25% within one month.

In this real-world implementation of HIV self-testing in 2017, over 10 000 self-tests were conducted. Of the 28% self-testers who self-reported their results, 15% had reactive results, suggesting that the programme is reaching higher-risk people. During this phase 230 people have received additional testing to confirm their status, and 81% (186) of these have enrolled in treatment and care.

The Safe Box project has distributed this self-test kit in five Russian cities.

Source: Evgeny Pisemsky, Phoenix PLUS, Russian Federation

There are several approaches to delivering HIV self-testing. They include facility-based or community-based distribution, secondary distribution through sexual or social networks, integration with related health programmes and interventions, workplace programmes, distribution through pharmacies, vending machines or kiosks, the Internet, and distribution through other public and private sector channels *(13)*. Which approaches are most appropriate depends on the context, setting and population that the programme has prioritized. When taking decisions to implement HIV self-testing, it is also important to consider how HIV self-testing can complement existing HIV testing services and address any coverage gaps in current programmes *(13)*. Box 3 summarizes Viet Nam's experience implementing and scaling up HIV self-testing.

Box 3. SCALING UP HIV SELF-TESTING: EXPERIENCE IN VIET NAM

With support from WHO, the Viet Nam Ministry of Health piloted community-based HIV testing, including lay provider testing and self-testing, in Can Tho City and Thai Nguyen province in 2017. Peer educators from three key populations – female sex workers, men who have sex with men and people who inject drugs – received training to provide HIV testing services including self-testing. HIV self-testing observed and supported by community providers began in July 2017. In June 2018, broader implementation was rolled out; community providers conduct brief demonstrations and provided individuals with self-test kits to take home. HIV testing was integrated with testing for syphilis and hepatitis C. Testing services were offered at various locations including peer educators' homes, a coffee shop and, if requested, participants' homes. Peer educators are available to provide support via text messages and telephone during or after self-testing.

In this period 892 people self-tested for HIV. Overall, 7.3% (65) of self-test results were reactive. Of those, 97% (63) were confirmed positive, and 94% (59) of these HIV-positive people initiated treatment. The success of this pilot project encouraged the government to revise the national guidelines to include lay provider HIV testing and HIV self-testing.

Source: Van Nguyen, WHO Country Office Viet Nam

Evidence suggests linkage to additional testing to confirm HIV status and treatment initiation following reactive self-test results can be at least equivalent to national linkage rates *(18, 22–25)*. HIV self-testing can also facilitate linkage to other prevention services, such as pre-exposure prophylaxis (PrEP) (Box 4). Support tools and innovative technologies, such as smartphone Apps, may also improve linkages to prevention and care after self-testing *(26)*.

Box 4. HIV SELF-TESTING PROMOTES TESTING AND LINKAGE TO PREVENTION AND TREATMENT AMONG FEMALE SEX WORKERS AND THEIR PARTNERS IN NAMIBIA

In 2018, Namibia endorsed HIV self-testing in its national guidelines and developed standard operating procedures. Following the guidelines, peers from key population groups were trained to distribute HIV self-test kits. Manufacturer instructions for use were provided in four local languages, Silozi, Rukwangali, Oshiwambo and Afrikaans.

Peers provided demonstrations while distributing HIV self-test kits to female sex workers in their communities. People who took self-test kits received two kits to encourage partner testing. Peer distributors also helped link people to further testing and treatment services as well as to prevention services and, when confirmed HIV-negative, to pre-exposure prophylaxis (PrEP).

A peer distributor demonstrates HIV self-testing to sex workers in Namibia.

Using this approach, between March and May 2018, peer distributors gave out 1475 kits. Some 813 recipients disclosed their test results to the peer distributors. Of those, 24 (2.9%) were confirmed to be HIV-positive, and 23 (96%) were linked to treatment. Sixty-two (8%) of those who were confirmed HIV-negative were linked to PrEP services.

Source: Taimi Amaambo, Society for Family Health; Denis Mali, USAID

What drives consumer preferences and demand?

Many individuals prefer self-testing due to its privacy, convenience and immediate results *(16–18)*. Data on consumer preferences when choosing self-test kits are limited, but cost and the accuracy of results may be key. In Australia online surveys using the Discrete Choice Experiment (DCE; a method to elicit relative preferences or relative importance of product characteristics based on alternate choice sets) among men who have sex with men found test accuracy and cost (more than half preferred a free test) were major factors that would influence choice of HIV self-tests *(27)*.

Test kit cost and accuracy seem to be the most important factors in consumers' choice of an HIV self-test.

Population-based qualitative research and DCE surveys among young people in Malawi and Zimbabwe also highlight preference for low-cost self-tests *(28)*. In Zambia DCE surveys among a population-based sample of adolescents and adults who had watched a short video on oral fluid self-testing indicated a willingness to pay for self-tests *(29)*. Those who had tested within the past 12 months were willing to pay the equivalent of US$ 3.30 for a self-test kit, while those who had not tested recently were willing to pay US$ 4.60. These and similar findings suggest that price of HIV self-tests could be a barrier to wider and equitable access to HIV self-testing *(30–34).*

Based on the limited information available from DCE surveys, specimen type – oral fluid or blood – does not seem to have a major influence on choice among HIV self-test kits *(27, 28)*. However, there is some evidence from cross-sectional and qualitative studies that certain demographic and population groups, such as men who have sex with men, female sex workers and people who inject drugs, may prefer one type or the other *(35–37)*. Field studies are ongoing in the HIV Self-Testing Africa (STAR) Initiative to further explore consumer preferences.[1] Diversifying the choice of available self-tests and specimen types in national programmes will likely make testing accessible and appealing to more people and also will strengthen the security of supply *(38)*.

[1] See the STAR Initiative public protocols for further details: http://hivstar.lshtm.ac.uk/.

Developments in HIV self-testing policy and implementation

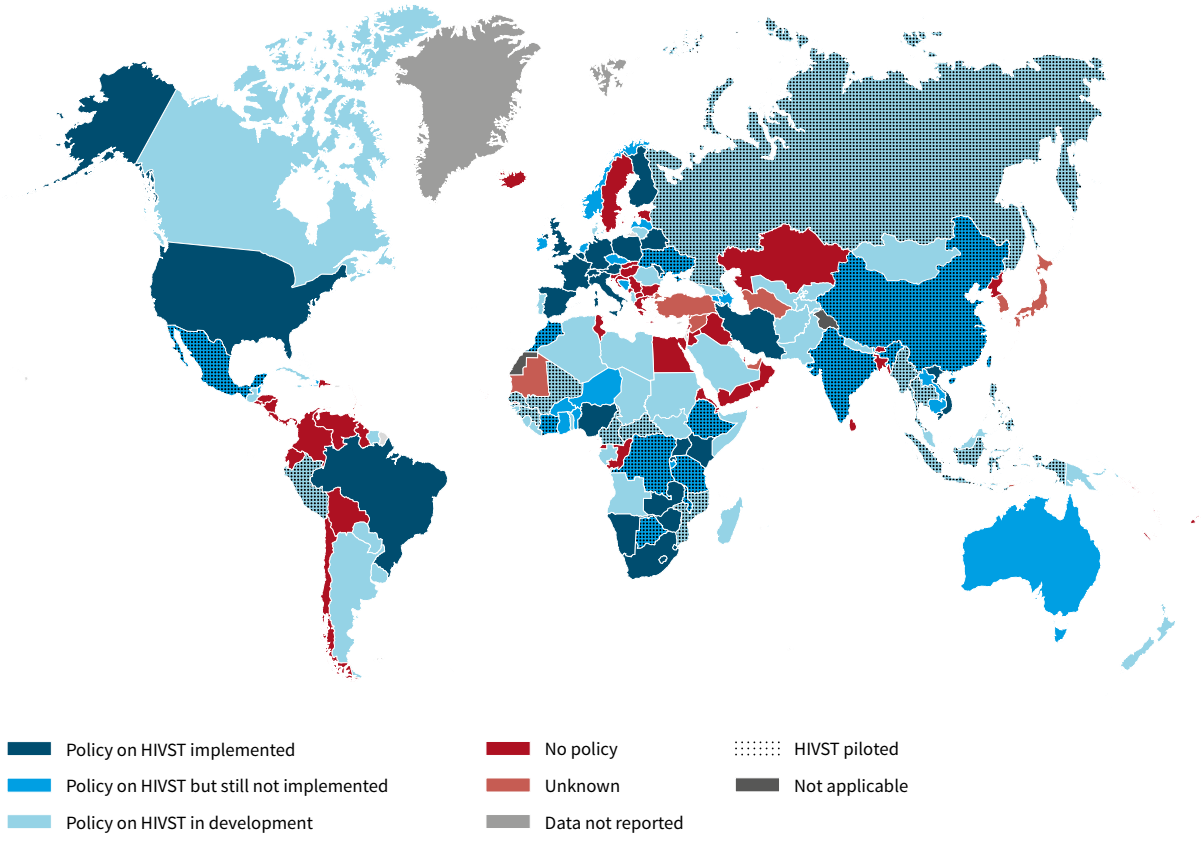
More and more countries are adopting HIV self-testing policies and introducing self-testing. Following release of the WHO guidelines in 2016, the number of countries with policies supporting self-testing has grown from 16 in July 2016 to 59 as of June 2018 *(38–40)* (Fig. 1). Another 53 countries report HIV self-testing policies are under development, with many to be completed later in 2018.

59 countries have self-testing policies, another 53 are developing policy, and 28 have implemented self-testing.

Despite favourable national policy changes, programme implementation of HIV self-testing is limited but increasing. In 2018, 28 countries are implementing HIV self-testing services, increasing from 13 in 2017, about two-thirds *(18)* of them being upper middle- or high-income countries. The gap between policy uptake and programmatic implementation often reflects the time required for operationalizing policies, including budgeting, funding procurement, selecting products, registering them and establishing supply chains and distribution processes. The gap is also due to insufficient evidence and lack of national-level investment cases to guide implementation and scale-up decisions. In some settings, planned/ongoing pilot and demonstration projects will generate evidence to inform national programmes and investment cases as well as priorities for donor funding.

FIGURE 1.

MAP OF COUNTRIES ACCORDING TO HIV SELF-TESTING POLICY AND IMPLEMENTATION SITUATION, AS OF JUNE 2018



Countries with HIV self-testing implemented* (n=28)

Austria, Belarus, Belgium, Brazil, Eswatini, Finland, France, Germany, Iran (Islamic Republic of), Italy, Kenya, Lesotho, Luxembourg, Malta, Namibia, Nigeria, Poland, Republic of Moldova, Rwanda, South Africa, Spain, Eswatini, Switzerland, Uganda, United Kingdom, United States of America, Viet Nam, Zambia, Zimbabwe.

Countries with a supportive policy but HIV self-testing not implemented* (n=31)

Armenia, Australia, Azerbaijan, Belize, Benin, Bosnia and Herzegovina, Botswana, Burkina Faso, Burundi, Cambodia, China, Côte d'Ivoire, Czech Republic, Democratic Republic of the Congo, Ethiopia, Ghana, Haiti, India, Ireland, Lao People's Democratic Republic, Latvia, Malawi, Mauritius, Mexico, Monaco, Morocco, Netherlands, Niger, Norway, Ukraine, United Republic of Tanzania.

Countries with HIV self-testing policies under development (n=53)

Afghanistan, Albania, Algeria, Angola, Argentina, Bahamas, Cameroon, Canada, Central African Republic, Chad, Cuba, Denmark, Gabon, Georgia, Guatemala, Guinea, Guinea-Bissau, Indonesia, Jamaica, Kyrgyzstan, Liberia, Libya, Lithuania, Madagascar, Malaysia, Mali, Mongolia, Mozambique, Myanmar, Nepal, New Zealand, Pakistan, Papua New Guinea, Paraguay, Peru, Philippines, Portugal, Romania, Russian Federation, Saudi Arabia, Senegal, Seychelles, Sierra Leone, Singapore, Somalia, South Sudan, Sudan, Suriname, Tajikistan, Thailand, Togo, Uruguay, Uzbekistan.

Global AIDS Monitoring (UNAIDS/WHO/UNICEF) and WHO HIV Country Intelligence Tool, 2018

*Overall 59 countries have a supportive of HIV self-testing policy

HIV self-testing procurement forecast

Forecast methodology and assumptions

The HIV self-testing global market forecast covers the period 2017–2020 inclusive and consists of "public sector" and "private sector" forecasts, with conservative, moderate and aggressive scenarios for each. The forecast considers 99 countries, accounting for more than 85% of the global burden of HIV. The public sector forecast is based on a foundation of planned procurements and a range of incremental estimates derived from interpretation of HIV self-testing policy adoption and implementation taking place in countries. The private sector forecast is based on an amalgamation of manufacturer-provided HIV self-test sales data and forecast volumes, which were standardized to align with forecast periods and avoid duplication. Annex 1 details the forecast methodology.

The public sector is expected to account for 55% of the total global HIV self-test market in 2020.

The foundation of HIV self-test planned procurement and donor funding that underpins the 2017–2020 forecast was provided predominantly by Unitaid, the Global Fund and PEPFAR. The forecast does not yet incorporate government funding. This foundation of actual data was overlaid with a variety of incremental and mutually exclusive estimates that attempt to model:

- the volume of HIV self-tests that could be expected per country with committed donor funding;
- the minimum baseline of continued HIV self-test volumes per country regardless of funding;
- the volume of HIV self-tests that could be expected for countries that have adopted an HIV self-testing policy but as of May 2018 had not yet started implementation;
- the volume of HIV self-tests that could be expected for countries that have adopted a HIV self-testing policy and are scaling up their implementation.

Key assumptions included in these estimates that have a significant impact on forecast volumes include:

- HIV self-test volumes for the five largest-volume countries will be flat from 2019 through 2020.
- Countries that are expected to scale up HIV self-test volumes will do so to at least 2.5% of 2-year (2016/2017) average HIV rapid diagnostic test (RDT) volumes in 2018 and at most 7.5% of the same HIV RDT volumes by 2020.

For the private sector forecast, future volumes were estimated by supplementing historical sales volumes with reported sales forecasts per country. Inputs into the private sector forecast were informed by discussions with several manufacturers, with sales data from different manufacturers covering 24 different countries incorporated into the forecast. No data were received for lower-income countries, and so they do not form part of the private sector forecast. The data provided by manufacturers were standardized to a consistent period, and inconsistencies were removed. This process resulted in the original amalgamated data being reduced by a little more than 2 million tests to arrive at the moderate private sector forecast.

HIV self-testing forecast summary

Global HIV self-test procurement volumes first exceeded 1 million tests in calendar year 2017 and are estimated to grow rapidly to 16.4 million (12.9 million – 19.3 million) by the end of 2020 (Fig. 2, Table 1). The public sector is estimated to account for 9.1 million (6.3 million – 11.2 million) self-tests in 2020. The private sector market is forecast to contribute 7.3 million (6.6 million – 8.0 million) self-test sales in 2020. These total volumes, forecast for 2020, represent a three-year compound annual growth rate (CAGR) of 289% (252% – 312%) from a low base at the end of 2017. Despite such projected growth through 2020, HIV self-test volumes reflect a small portion (4.6%) of the 360 million total HIV RDT volumes forecast for this same period.[1] The forecast for self-tests reflects expected growth in both public and private sectors up to and beyond 2020 due to the rapidly changing regulatory and policy environment in countries and the expectation that HIV self-tests will increase as a proportion of total RDT volumes. Further details of HIV self-testing public and private sector forecast follow.

[1] Avenir Health forecast volumes of 360 million RDTs globally by 2020, presented at AIDS Medicines and Diagnostics Service (AMDS), Geneva, April 2018.

FIGURE 2.

GLOBAL HIV SELF-TEST PROCUREMENT FORECAST

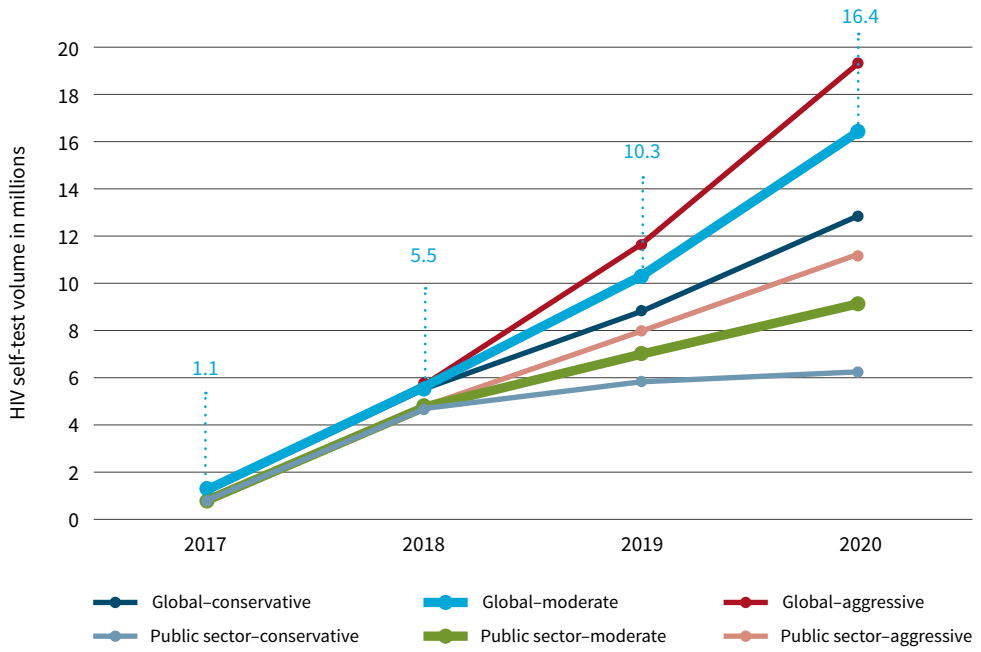


TABLE 1.

Global HIV self-test forecast volumes,* 2018–2020, by market sector and scenario

Market sector and scenario	2018	2019	2020
Conservative forecast			
Public sector	4 700 000	5 900 000	6 300 000
Private sector (moderate -10%)	700 000	2 900 000	6 600 000
Global	5 500 000	8 800 000	12 900 000
Moderate forecast			
Public sector	4 700 000	7 000 000	9 100 000
Private sector	800 000	3 300 000	7 300 000
Global	5 500 000	10 300 000	16 400 000
Aggressive forecast			
Public sector	4 700 000	8 000 000	11 200 000
Private sector (moderate +10%)	900 000	3 600 000	8 000 000
Global	5 600 000	11 600 000	19 300 000

* Component values were rounded before being aggregated. Thus, values presented may differ from true totals.

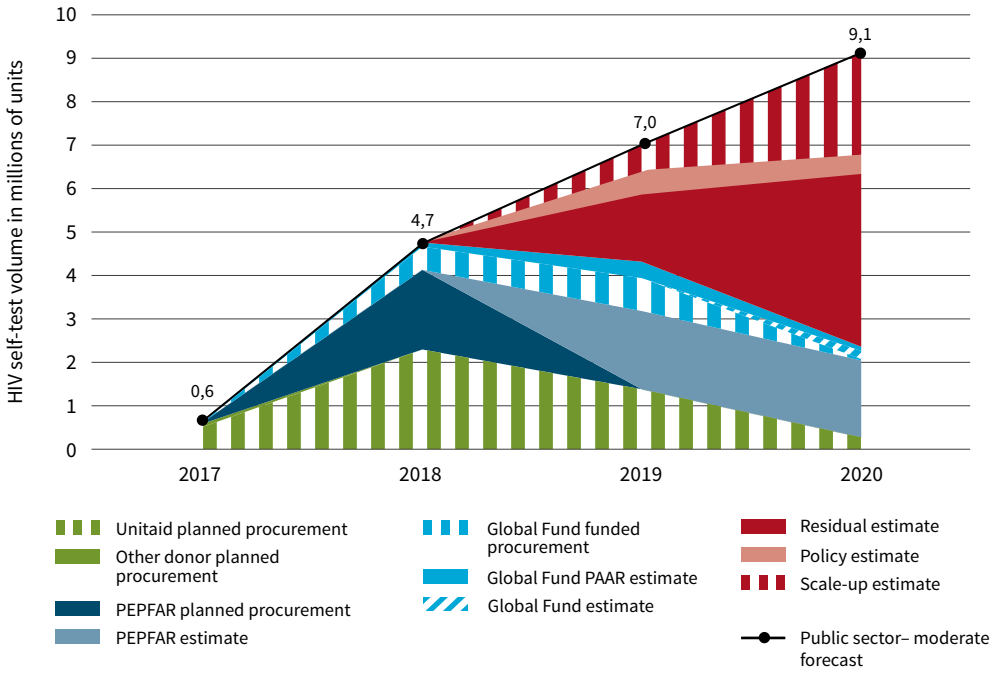
HIV self-testing public sector forecast

HIV self-testing public sector procurement by governments and donors is expected to grow to at least 4.7 million self-tests in 2018. By 2020 these volumes are expected to grow to 9.1 million (6.3 million – 11.2 million) (Fig. 3). The immediate growth is driven largely by confirmed procurement of HIV self-tests by donors including Unitaid and PEPFAR in five countries (Kenya, Malawi, South Africa, Zambia and Zimbabwe) where HIV self-testing is already available and implemented (Fig. 4). These volumes provide a somewhat stable foundation for the HIV self-testing market.

From 2019 onwards, the market is expected to grow and diversify, with other LMICs expected to procure 46% (4.2 million) of the total 9.1 million public sector tests in 2020. This diversification is expected to be driven by countries that are scaling up HIV self-testing with 2.4 million additional self-tests attributed to them in the moderate forecast scenario in 2020. Annex 2 presents data tables for the public sector forecast scenarios and estimates, and Annex 3 presents a list of countries included in the public sector forecast.

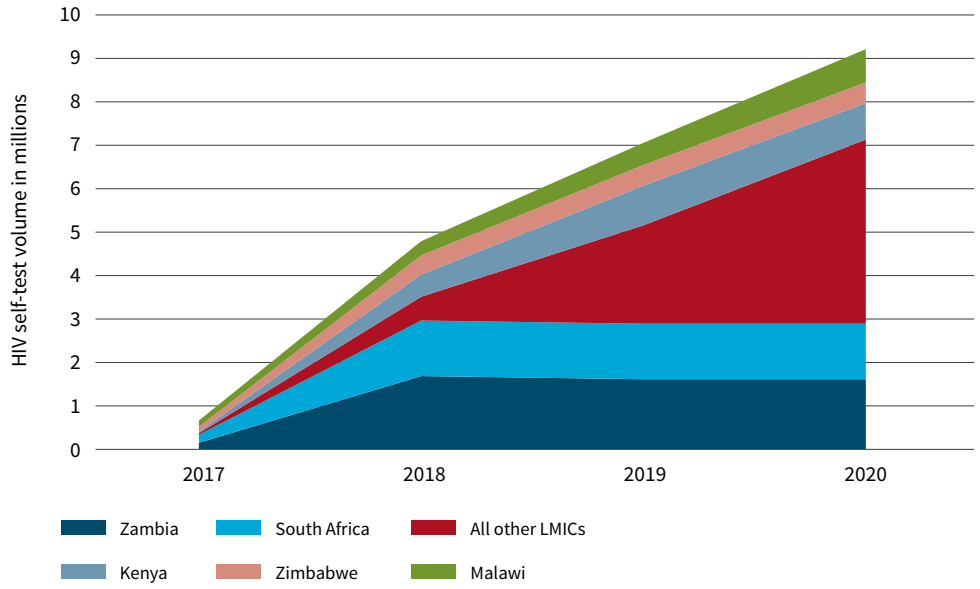
FIGURE 3.

PUBLIC SECTOR MODERATE FORECAST SCENARIO, 2017-2020, BY PLANNED AND ESTIMATED HIV SELF-TEST PROCUREMENT VOLUMES



PEPFAR: President's Emergency Program For AIDS Relief; **PAAR:** prioritized above allocation request.

FIGURE 4.
PUBLIC SECTOR MODERATE FORECAST SCENARIO 2017-2020, BY COUNTRY



LMIC: Low- and middle-income countries.

HIV self-testing private sector forecast

The HIV self-test private sector market is estimated to reach 7.3 million self-test kits (6.6 million – 8.0 million) by 2020 (Fig. 5). This forecast reflects steady growth in HIV self-test volumes in the three early-adopting high-income countries (France, the United Kingdom and the United States) and manufacturers' optimism about the implementation and scale-up of HIV self-testing in the private sector in additional countries. This optimism has a near-term focus in the Americas Region (46% of total private sector volumes forecast for 2019) as well as Europe (27% of total private sector volumes forecast for 2019). Beyond 2019, growth is expected to accelerate as more densely populated markets in South-East Asia and the Western Pacific regions (49% of total private sector volumes forecast for 2020) start to drive volumes. Aligned with this regional growth is the expectation that upper-middle income countries will drive the forecasted private sector volumes (Fig. 6). Annex 4 presents details.

Private sector sales are projected to reach 7.3 million tests by 2020, reflecting steady sales growth in the three early-adopting high-income countries plus introduction and scale-up elsewhere.

FIGURE 5.
PRIVATE SECTOR MODERATE FORECAST SCENARIO, 2017–2020, BY WHO REGION

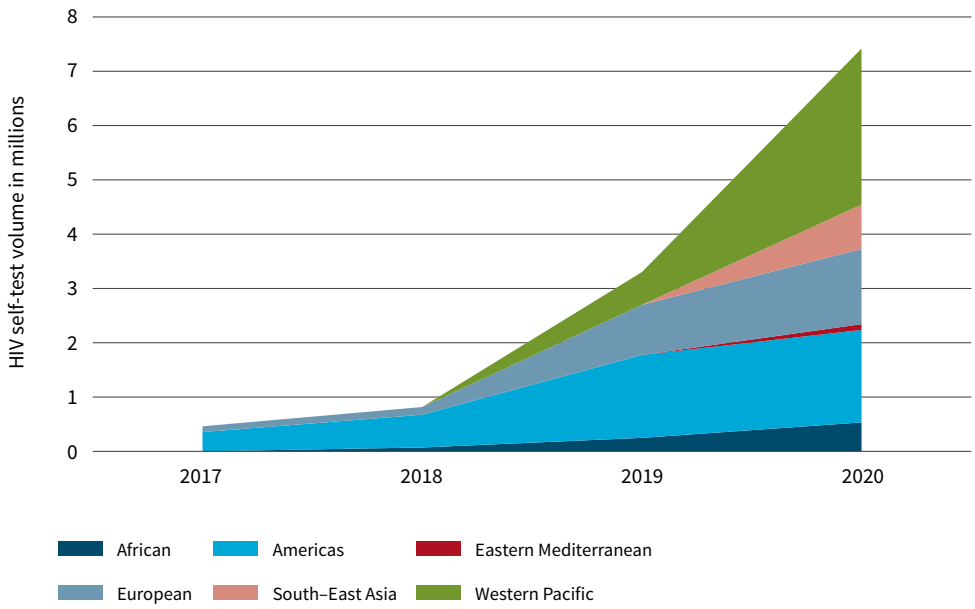
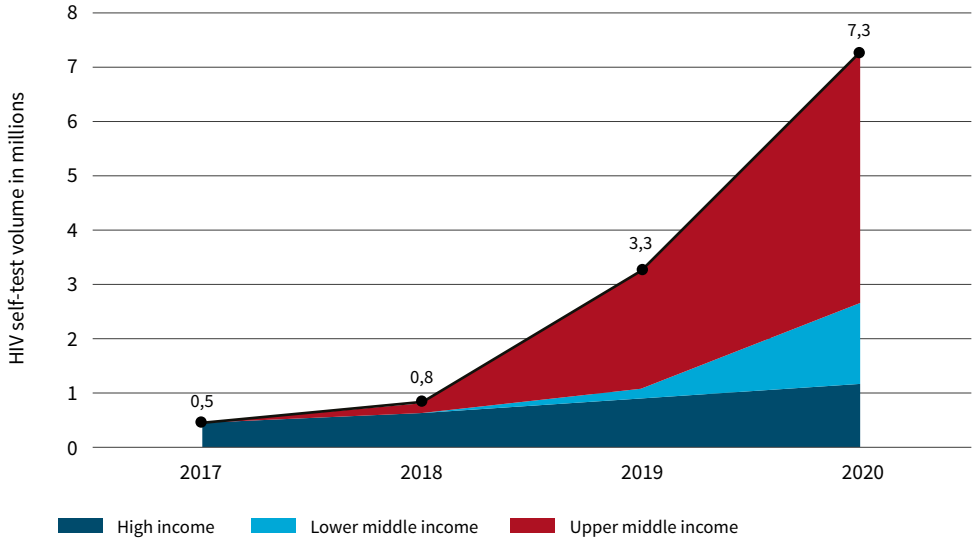


FIGURE 6.
PRIVATE SECTOR MODERATE FORECAST SCENARIO, 2017–2020, BY COUNTRY INCOME CLASSIFICATION*



*County income classifications are based on the World Bank July 2017 classification. See https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups.

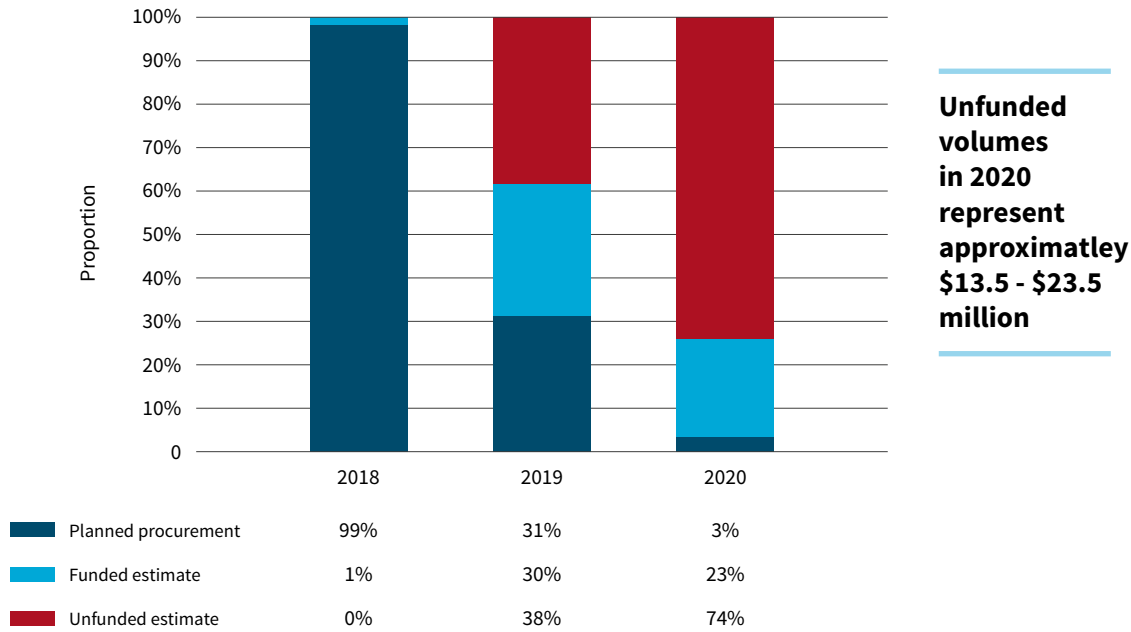
HIV self-testing public sector funding situation

The public sector moderate forecast indicates 7 million self-test kits will be procured in 2019 and 9.1 million in 2020. Of the forecast volumes in 2019, 2.2 million (31%) are already planned for procurement, and an estimated additional 2.1 million (30%) are funded through a specific donor or funding source. The remaining 2.7 million self-tests (39%) for 2019 are unfunded, meaning there are no known resources committed to their procurement (Fig. 7). For 2020, 74% of projected self-test kit volumes are not yet funded. Annex 5 presents a full break-down of donor funding shares by country.

Although a large proportion of forecast volume in 2020 is estimated to be unfunded, the expected funding required to fill this gap is not large – US$ 13.5 to US$ 23.5 million – especially in comparison with the funding spent on the total professional use RDT market.

FIGURE 7.

PUBLIC SECTOR MODERATE FORECAST SCENARIO, 2017–2020, BY FUNDING SITUATION



Unfunded volumes in 2020 represent approximatley $13.5 - $23.5 million

HIV self-testing public sector procurement and funding timelines

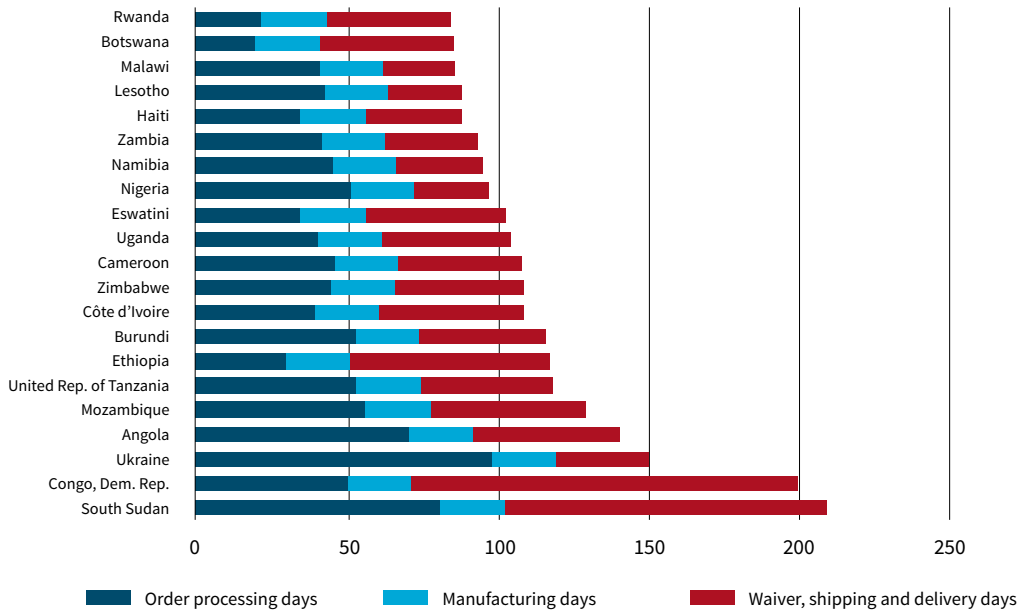
Public sector financing, procurement and delivery of RDTs is a complex multi-step and multi-stakeholder process. Depending on the funding source and procurement method, this process can vary considerably and could slow the growth of the HIV self-testing market prior to 2020. Typically, there are two main components to this process – financing and procurement. The following analysis of Global Fund financing timelines and PEPFAR procurement timelines provides an illustrative indication of how long the combined financing and procurement process can take. These processes are separate and sequential and should not be compared.

Acquiring the financing needed for HIV self-test procurement for any given country can take more than two years, although it varies by funder. Based on an estimate of the expected procurement dates for four Global Fund grant requests specifically related to the funding and procurement of an expected 1.4 million HIV self-tests, the average elapsed time from the start of grant evaluation by the Global Fund Technical Review Panel (TRP) to the estimated procurement date is 503 days (range: 357 – 633 days). This does not include the time required to prepare the grant submission.

The Global Health Supply Chain (GHSC) Program is the main procurement agent for PEPFAR and USAID purchases of RDTs including HIV self-tests. The average lead-time to process and deliver an order for RDTs (professional use or HIV self-test) as of June 2018 has been 115 days across 21 countries for orders received by GHSC in 2017 and 2018, excluding outliers. For most countries (16 of 21), total processing, waiver and delivery elapsed time has ranged between 80 and 120 days; only five countries exceeded 120 days (Fig. 8). The average includes an estimated manufacturing period of 21 days and starts from the time that GHSC receives a price request. See Annex 6 for additional details.

FIGURE 8.

GLOBAL HEALTH SUPPLY CHAIN SALES ORDER PROCESSING AND DELIVERY TIMELINES FOR HIV RAPID DIAGNOSTIC TESTS, 2017–2018, BY COUNTRY



Note: Waiver days relate to the elapsed time required to request and obtain custom import waivers where necessary.
Source: Peter Smith (GHSC-RTK), personal communication, April 2018.

HIV self-test volumes as a proportion of total RDT volumes

Both the moderate and aggressive public sector forecasts are significantly influenced by assumptions regarding the volume of HIV self-tests as a proportion of total RDT volumes. The moderate forecast includes an estimate that assumes countries scaling up HIV self-testing would achieve HIV self-test volumes of 2.5% – 5% of total RDT volumes. The aggressive scenario assumes a range of 5% – 7.5%. These assumptions are supported by the following information. The global HIV self-test market forecast constitutes only a small part of total RDT market forecast volumes – 1.6% in 2018, 2.9% in 2019 and 4.6% in 2020 (Fig. 9). The public sector moderate forecast for HIV self-tests constitutes 8% of a comparable segment of the total RDT market, while HIV self-testing forecast volumes amount to only 4.8% of total RDT volumes in LMICs other than the five highest volume countries (Kenya, Malawi, South Africa, Zambia and Zimbabwe). In these five key countries in 2020, the HIV self-test public sector moderate forecast constitutes 18.8% of average 2016 and 2017 RDT volumes reported to WHO but ranges widely from 10% in South Africa to 35% in Kenya (Fig. 10). The current proportion of HIV self-tests to total RDT volumes globally

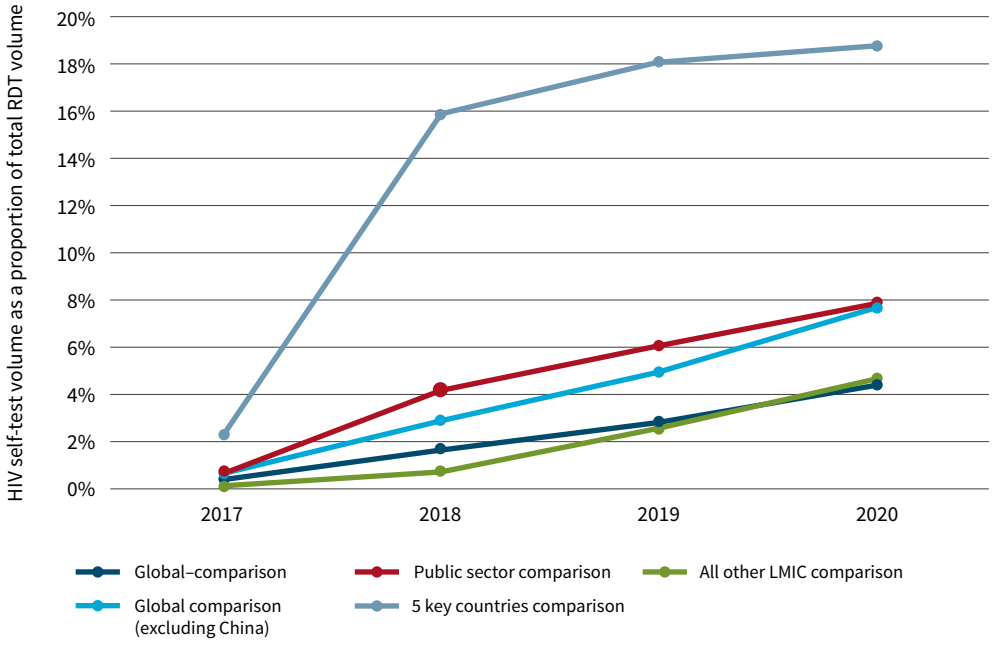
and in these five key countries suggests that the assumptions used in the forecast are conservatively situated in a wide band of current values and that there is precedent for HIV self-test volumes to grow beyond the assumed proportions.

HIV self-tests are projected to account for an increasing but still small fraction of all HIV RDTs by 2020.

Current donor and country HIV self-testing implementation and plans, reported to the WHO, suggest that steady growth will continue through and beyond 2020. This growth is driven by countries implementing HIV self-testing for the first time and countries that have already started scaling up their volumes. This, as well as projected slowing of overall professional-use HIV RDT scale-up in 2020 and beyond, may signal considerable opportunities for further growth in the HIV self-test market beyond 2020. While it is too early to tell in this forecast, this should be further explored in the future forecasts. Annex 7 presents calculation details and data values on HIV self-test volumes as a proportion of total RDT volumes.

FIGURE 9.

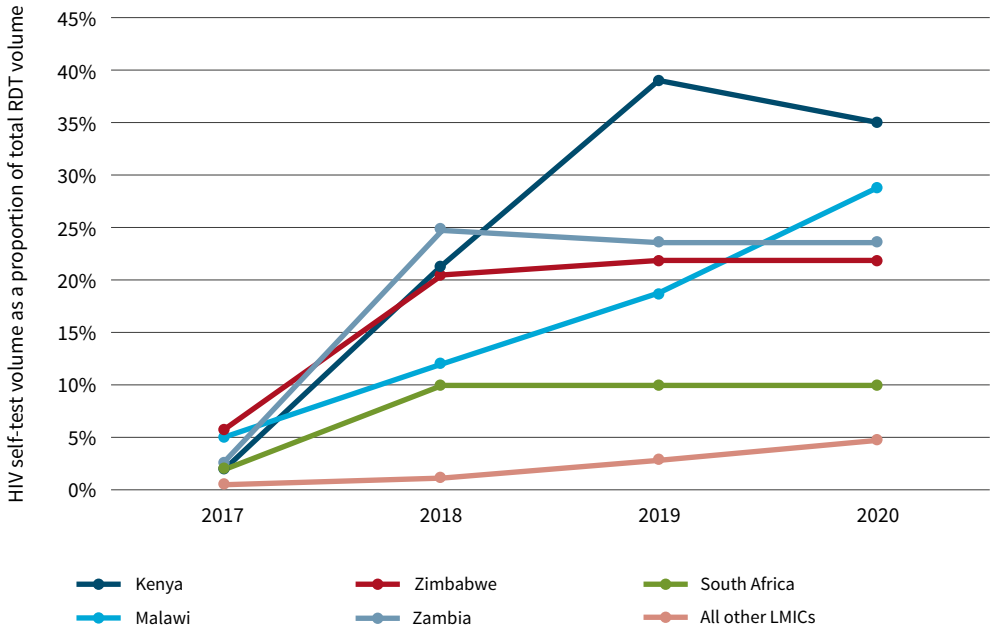
HIV SELF-TEST VOLUMES AS A PROPORTION OF TOTAL RAPID DIAGNOSTIC TEST VOLUMES, 2017–2020



Note: Key countries include Kenya, Malawi, South Africa, Zambia and Zimbabwe.
For detailed data and definitions of each comparison please refer to the Annex 7.

FIGURE 10.

PUBLIC SECTOR MODERATE FORECAST SCENARIO AS A PROPORTION OF TOTAL RDT VOLUMES, 2017-2020, BY COUNTRY.



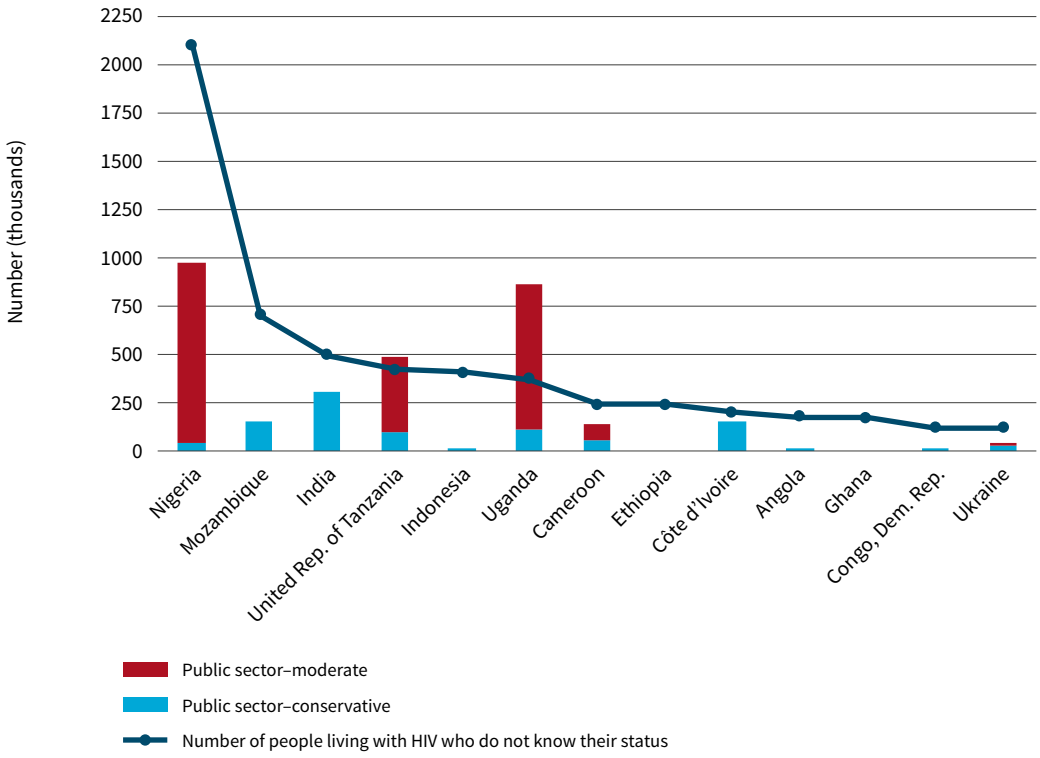
Note: Total rapid diagnostic test volume data for South Africa come from PEPFAR; all other country data come from the WHO Global Aids Progress Response Reporting Survey.
For detailed data and definitions of each comparison please refer to the Annex 7.

Additional room for growth: high burden countries with limited procurement plans

Of the 99 countries considered in the global forecast, 13 have more than 100 000 people living with HIV who do not know their status (a proxy for need) and have relatively low forecasted HIV self-test volumes (Fig. 11). In addition, six countries that have a comparatively high need for testing have not been included in the forecast due to lack of information regarding their HIV self-testing programmes. All these countries present opportunities for the HIV self-testing market to grow.

FIGURE 11.

HIV SELF-TEST PUBLIC SECTOR CONSERVATIVE FORECAST VOLUMES AND NUMBER OF PEOPLE LIVING WITH HIV WHO DO NOT KNOW THEIR STATUS IN COUNTRIES WITH LIMITED HIV SELF-TEST PROCUREMENT TO DATE



HIV self-test kits available in the market or under development

Methodology

WHO collected the information on HIV self-test kits from manufacturers of diagnostics. The information was collected from all manufacturers through one-on-one meetings either in person or virtually. The manufacturers of HIV self-tests were identified from previous HIV self-test landscape reports. Additional products (in selected countries or in development) were identified through consultation with other partners. The manufacturers reviewed information related to their products prior to publication.

The same self-test kits sold in different packaging by one manufacturer are considered different products for regulatory purposes, but have been counted as one product for the purpose of this report. The exception is two self-test kits by OraSure Technologies, which are counted separately as the design, product characteristic and regulatory approvals all substantially differ. HIV self-tests were classified into the following three categories depending on their approval status and whether already marketed or under development:

- HIV self-tests kits prequalified by WHO, approved by a regulatory authority in one of founding-member countries of the International Medical Device Regulators Forum or eligible for procurement on recommendation of the Unitaid/Global Fund Expert Review Panel for Diagnostics (Box 5);
- HIV self-test kits with national-level approval and available in selected countries;
- HIV self-test kits under development and not yet available in the market.

Box 5. HIV SELF-TEST ASSESSMENT BY WHO PREQUALIFICATION AND THE EXPERT REVIEW PANEL FOR DIAGNOSTICS

The procurement policies of major international funders for HIV programmes (the Global Fund, PEPFAR and Unitaid) require in-vitro diagnostic devices (IVDs), including HIV self-tests, to be manufactured according to the applicable standards of the International Organization for Standardization (ISO) or equivalent standards and for the IVD to be stringently reviewed and approved. In addition, recommendation of the Expert Review Panel for Diagnostics (ERPD)[1] provides temporary, time-limited eligibility for procurement of IVDs in anticipation of an assessment for WHO prequalification. The ERPD is supported by Unitaid and the Global Fund and hosted by WHO.

The requirements for WHO prequalification of an HIV self-test kit involve an assessment of a product dossier submitted by the manufacturer that contains comprehensive information on analytical performance characteristics, clinical performance characteristics (diagnostic sensitivity and specificity) and usability (label comprehension, self-test results interpretation and a study of observed untrained users). In addition, a laboratory performance evaluation and on-site inspection of the manufacturing facility are conducted to evaluate manufacturing quality and risk management (41). Full details and requirements for prequalification are available on the WHO website.[2]

Currently, WHO has prequalified one HIV self-test.[3] WHO is currently evaluating several other HIV self-test products.

HIV self-tests kits prequalified by WHO, approved by a regulatory authority in one of the founding-member countries of the International Medical Device Regulators Forum or eligible for procurement on recommendation of the Unitaid/Global Fund Expert Review Panel for Diagnostics

As of July 2018 eight HIV self-test products have either been prequalified by WHO, approved by a stringent regulatory authority, or recommended by ERPD.

As of July 2018 eight HIV self-test products have been prequalified by WHO, approved by a stringent regulatory authority in one of the founding member countries of the International Medical Device Regulators Forum (IMDRF),[4] or recommended for procurement by ERPD (Table 2). Two of these products are oral fluid-based and six are blood-based self-tests. These products are available in the public and private sectors in several countries including the United States, the United Kingdom, other European countries and a number of countries in Africa. See Annex 8 for detailed product specifications.

[1] More information can be found at https://www.theglobalfund.org/en/sourcing-management/updates/2017-07-12-hiv-self-testing-kits-assessed-for-eligibility for-procurement-by-the- expert-review-panel/

[2] Technical Specifications Series for submission to WHO Prequalification – Diagnostic Assessment: Human immunodeficiency virus (HIV) rapid diagnostic tests for professional use and/or self-testing. http://www.who.int/biologicals/expert_committee/TSS-1_FINAL_Post_ECBS.pdf

[3] http://www.who.int/diagnostics_laboratory/evaluations/170720prequalified_product_list.pdf?ua=1

[4] The founding members of the IMDRF are Australia, Canada, the European Union, Japan and the United States of America. The IMDFR was previously known as the Global Harmonization Task Force (GHTF). More information is available at http://www.imdrf.org/ghtf/ghtf-archives.asp

TABLE 2.

HIV self-test kits prequalified by WHO, approved by a regulatory authority in one of founding-member countries of the International Medical Device Regulators Forum or eligible for procurement on recommendation of Unitaid/Global Fund Expert Review Panel for Diagnostics

Test name (manufacturer/ supplier)	Test generation[a]	Specimen	Sensitivity	Specificity	Approval status	Markets	Price in US$ per test
atomo HIV Self Test (Atomo Diagnostics, Australia)	3rd	Fingerstick/ whole blood	99.7%	99.7%	CE mark, ERPD (Category-3)[b]	Kenya, South Africa	Public sector: $ 3 (depends on volume)
autotest VIH® (three packaging formats) (AAZ Labs, France)[c]	2nd	Fingerstick/ whole blood	100.0%	99.8%	CE mark	Registered and available in 15 European countries[d]	HIC retail: $ 20–28 Distributors/NGOs: $ 8–15 (depends on packaging format)
BioSURE HIV Self Test (hard case & soft case) (BioSURE, United Kingdom Ltd)[c]	2nd	Fingerstick/ whole blood	99.7%	99.9%	CE mark, ERPD (Category-3)[b,e]	South Africa, United Kingdom	HIC retail: $ 42–48 HIC public sector: $ 7.50–15 LMIC retail: $ 11.75
Exacto® HIV Screening Test (Biosynex, France)	3rd	Fingerstick/ whole blood	99.99%	99.90%	CE mark	Europe[d]	Not available
INSTI® HIV Self Test (box & pouch) (bioLytical Lab., Canada)[c]	2nd	Fingerstick/ whole blood	Box: 100.0% Pouch: 99.8%	Box: 99.8% Pouch: 99.5%	CE mark, ERPD[c] (Category-3)[b]	Europe[d]	Price: $ 3–12 MSRP: $ 7–36 (Prices depend on packaging format, volumes and market region)
OraQuick® In-Home HIV Test (OraSure Technologies, USA)	2nd	Oral fluid	91.7%	99.98%	FDA	USA	HIC retail: $ 40 Public sector prices vary.
OraQuick® HIV Self Test (OraSure Technologies, USA)	Not available[f]	Oral fluid	FDA: 91.7%[g] CE: 100%	FDA: 99.98%[g] CE: 99.6%	CE Mark, WHO PQ[h]	Kenya, South Africa, Uganda, Zambia, Zimbabwe	LMIC ex-works[i]: $ 2 for 50 countries[j]
SURE CHECK® HIV Self Test (Chembio Diagnostic Systems Inc., USA)	2nd	Fingerstick/ whole blood	Not available	Not available	ERPD (Category-3)[b]	Not available	Not available

CE: Conformité Européenne; **ERPD:** Expert Review Panel for Diagnostics; **FDA:** United States Food and Drug Administration; **HIC:** high-income country; **LMIC:** Low- and middle-income country; **MSRP:** manufacturer's suggested retail price; **NGO:** nongovernmental organization; **PQ:** prequalification; **USA:** United States of America; **WHO:** World Health Organization.

Note: Product details based on information provided by the manufacturers at the time of report preparation.

[a] Test generation is based on product design and formulation of reagents (2nd generation: Protein A-conjugate; 3rd generation: recombinant antigen-conjugate) in accordance with WHO prequalification criteria.

[b] Additional information is available at: https://www.theglobalfund.org/media/5878/psm_productshiv-who_list_en.pdf.

[c] Different packaging formats are considered different products for regulatory purposes but have been considered a single product for the purpose of this report.

[d] Names of countries not available

[e] ERPD approval expired February 19 2018; currently under reassessment.

[f] Pending outcome of WHO prequalification review of change notification.

[g] United States FDA approval required unobserved use testing relying on individuals to correctly report their test results without a trained professional confirming the self-reported result. Additional information is available at: https://www.fda.gov/biologicsbloodvaccines/bloodbloodproducts/approvedproducts/premarketapprovalspmas/ucm310436.htm

[h] Additional information is available at: http://www.who.int/diagnostics_laboratory/evaluations/pq-list/170720_final_amended_pqdx_0159_055_01_oraquick hiv_self_test_v2.pdf?ua=1.

[i] Ex-works prices are determined at the manufacturer's factory and do not include any delivery, distribution, taxes or commission charges.

[j] A list of countries is available at http://www.orasure.com/products-infectious/products-infectious-oraquick-self-test.asp.

As of July 2018 only one HIV self-test has been prequalified by WHO. The United States Food and Drug Administration has approved one self-test. Five self-tests have received the CE mark for sale in European Union markets, three of which are also recommended for procurement in LMICs by ERPD for operational research. One of the eight self-tests has ERPD approval only, with neither WHO prequalification nor stringent regulatory authority approval (Table 2). Several of these self-tests are currently undergoing assessment for WHO prequalification.

The price per HIV self-test in LMICs ranges from US$ 2 to US$ 12 per test in the public sector and US$ 7 to US$ 12 in the private sector.

The price per self-test kit varies considerably depending on setting, market and packaging format. In high-income countries, where HIV self-tests are typically sold in the private sector through pharmacies and the Internet, the price of self-tests ranges from US$ 20 to US$ 48 per test. In contrast, HIV self-tests are available at relatively low prices in LMIC settings. In the private sector in LMICs prices range from US$ 7 to US$ 12 per test, and in the public sector from US$ 2 to US$ 12 per test.The lowest price, US$ 2 per test (ex-works[1]) for the OraQuick® HIV Self-Test, results from an agreement between the Bill & Melinda Gates Foundation and OraSure Technologies in June 2017. The agreement makes public sector procurement possible at this price in 50 selected high HIV burden LMIC settings for a limited time.[2]

[1] Ex-works prices are determined at the manufacturer's factory and do not include any delivery, distribution, taxes or commission charges.
[2] List of countries available at http://www.orasure.com/products-infectious/products-infectious-oraquick-self-test.asp.

HIV self-test kits with national-level approval available in selected countries

Locally manufactured HIV self-tests with national-level approvals are appearing in some countries. For example, four locally manufactured HIV self-tests have been approved in Brazil (two oral fluid, one blood, one unknown), one in Nigeria (oral fluid) and one in Belarus (oral fluid) (Table 3). The quality and performance of these products are largely unknown. Box 6 describes the introduction in Belarus of a locally manufactured HIV self-test. Annex 9 provides full product specifications for several of these products.

TABLE 3.

HIV self-test kits with national-level approval in selected countries

Test name (manufacturer/supplier)	Specimen	Approval status	Availability	Price in US$
Action! (Orangelife Comércio e Indústria LTDA, Brazil)	Whole blood	ANVISA, Brazil (National Sanitary Surveillance Agency)	Brazil	Free-on-board*: $ 9.80
Alerta (Wama Diagnóstica, Brazil)	Whole blood	ANVISA, Brazil (National Sanitary Surveillance Agency)	Brazil	Not available
Amethyst HIV 1&2 Test Kit (Bedford Biotech Nigeria Ltd., Nigeria)	Oral fluid	Approved in Nigeria	Nigeria	$ 14 recommended market price. Prices for public sector and NGOs may vary.
HIV Detect (Eco diagnóstica, Brazil)	Oral fluid	ANVISA, Brazil (National Sanitary Surveillance Agency)	Brazil	Not available
Saliteste (Ebram Produtos Laboratoriais, Brazil)	Oral fluid	ANVISA, Brazil (National Sanitary Surveillance Agency)	Brazil	Not available
Unnamed test (Belarus)	Not available	Manufactured and approved in Belarus	Belarus	Not available

NGO: Nongovernmental organization.
Note: Product details based on information provided by the manufacturers at the time of report preparation.
* Free on board: This includes ex-works price plus freight cost to distributors.

Box 6. REPUBLIC OF BELARUS LAUNCHES AND PROMOTES HIV SELF-TESTING USING A LOCALLY MANUFACTURED KIT

The Republic of Belarus introduced HIV self-testing at pharmacies in 2017 using a locally manufactured product. Pharmacy staff and health-care workers were trained to provide information to clients who purchase self-tests. Instructions on how to self-test and what to do following a positive or negative self-test were developed and provided in the local language. Pharmacies in all regions of Belarus are currently selling the self-test at the equivalent of approximately US$ 2.9 per test.

The roll-out of self-testing was accompanied by large-scale campaigns to raise awareness about HIV and to encourage people to get tested. These campaigns included outdoor advertising at large-scale events with high visibility. For example, at the Minsk half-marathon the slogan, "It concerns even those who are not concerned" (translated from Russian) was launched to promote HIV self-testing.

As of April 2018, pharmacies had sold over 2 500 HIV self-tests. So far, 20 individuals who shared information came for further testing to confirm their status. Of these, 18 (90%) are known to have been confirmed HIV-positive.

Source: Elena Vovc, Antons Mozalevskis, Viatcheslav Grankov, WHO Regional Office for Europe

HIV self-test kits under development

The pipeline for HIV self-testing products continues to be rich and diverse. Based on reports from HIV diagnostic manufacturers, at least six HIV self-test products are under development (Table 4). Of these, three require a fingerstick/whole blood specimen, two use oral fluid specimens, and one would use a urine specimen. For one of the oral fluid self-tests, a version is under development that will be packaged so that users will have the option to use either oral fluid or whole blood specimen to self-test. Annex 10 presents full product specifications.

Three of the manufacturers have indicated a desire to obtain WHO prequalification. Several manufacturers indicated they are seeking additional national regulatory approvals and registration. The price range of emerging self-tests remain uncertain.

Additional unregulated HIV self-tests, largely of unknown quality and performance characteristics, continue to be available in some settings through informal channels, including the Internet and private pharmacies.

TABLE 4.

HIV self-test kits with national-level approval in selected countries

Test name (manufacturer/supplier)	Specimen	Plan for regulatory approval
Asanté™ HIV Self Test (Sedia Biosciences Corporation, USA)	Oral fluid (also, a version is under development that can test either an oral fluid or whole blood specimen in a single device)	Not available
AwareTM HIV-1/2 OMT Oral HIV Self Test (Calypte Biomedical, USA)	Oral fluid	Plan to apply for WHO PQ and CE mark
First Response HIV 1-2.0 Card Test (Self Test) (Premier Medical Corporation, India)	Whole blood	Plan to apply for WHO PQ
To be named (Abbott Laboratories, USA)	Whole blood	Not available
To be named (Beijing Wantai Biological Pharmacy Enterprise Co., Ltd., China)	Urine	National regulatory approval in China pending
To be named (Trinity Biotech, Ireland)	Whole blood	Not available

CE: Conformité Européenne; **PQ:** prequalification; **WHO:** World Health Organization.
Note: Product details based on information provided by the manufacturers at the time of report preparation.

Need for innovation to improve self-tests for HIV, as well as other conditions

The growing pipeline of HIV self-testing products is encouraging. However, there remains potential for further innovation. The evidence suggests that, although most self-testers are able to perform HIV self-testing correctly *(16)*, user errors are not uncommon *(30, 42, 43)*. There is potential to further optimize and improve self-test product performance, particularly simplified and painless sample collection, clear instructions, demonstrations and support tools, fewer steps, faster and easy to read results.

Interest is growing in developing multiplex tests, which can detect multiple diseases simultaneously.

Interest is growing in the development of new multiplex self-tests – self-test devices with the ability to test simultaneously for more than one disease using a single specimen and one test procedure or test run. The availability and introduction of multiplex self-tests may reduce missed opportunities for those who choose to self-test for HIV to screen for other conditions, thus maximizing the personal and public health benefit of self-testing. However, operational research will be needed to assess the balance between benefits offered by multiplex technologies against added complexity for users in interpreting and acting on their results. Possible combinations being explored include HIV, syphilis, hepatitis B and hepatitis C, among others. Currently, a small number of WHO-prequalified or stringently approved multi-disease rapid diagnostic assays are available for professional use *(44)*. For example, three HIV/syphilis combination professional-use RDTs have received the CE mark, and WHO has prequalified one of these. Three HIV, hepatitis B and C combination professional-use RDTs have received the CE mark. One CE-marked professional-use RDT can simultaneous detect HIV, syphilis, hepatitis B and C *(44)*. None of these has yet been adapted or approved for self-testing by a stringent regulatory authority.

Self-testing for sexually transmitted infections (STIs) is another possibility that needs exploration. Self-collection systems currently exist for certain STIs (chlamydia, gonorrhoea, human papillomavirous) *(45, 46)*. There are currently no approved self-tests for STIs, however. Thus, those who choose to self-test for HIV still need to visit facilities if they want STI testing. Further opportunities for innovation exist in developing self-testing device platforms that could be easily adapted for different diseases and conditions.

Barriers to and opportunities for HIV self-testing market growth

The market for HIV self-testing continues to evolve rapidly. The growing uptake of HIV self-testing policies and implementation is encouraging. Key drivers of market growth have been the release of the WHO guidelines, clarity in the WHO prequalification process and the prequalification of one self-test, ongoing product innovation and improvement, increased donor investment and price reductions in the public sector in LMIC settings. The five-fold increase in global HIV self-test volumes from about 1 million in 2017 to an estimated 5.5 million in 2018 testifies to recent progress (Box 7). Projections for growth to over 16 million in 2020 anticipate that the confluence of events will continue to propel rapid growth of the self-test market, with potential for public health impact as the result.

Box 7. PROGRESS IN THE HIV SELF-TESTING MARKET AND TECHNOLOGY SINCE 2017

The 2017 HIV self-testing market and technology landscape report made several recommendations to countries, national programmes, donors and diagnostics manufacturers in order to continue progress in HIV self-testing. Considerable progress has been made in some areas, while much work remains to be done in others. Below is a summary of advances over the past year in light of the 2017 recommendations.

Implementing and scaling up HIV self-testing through national programmes. *The number of countries with self-testing policies continues to grow rapidly (40 in July 2017 and 59 as of June 2018), as well as the number of countries implementing HIV self-testing through national programmes (13 in 2017 and 28 in 2018). While the progress is considerable, many countries have yet to implement and scale up self-testing. The lag between policy uptake and programmatic implementation reflects the time required to operationalize policies, including budgeting, funding procurement, selecting products, registering them and establishing supply chains and distribution processes. It also is partly due to national-level evidence gaps and lack of investment cases to show public health benefit that guide implementation and scale-up decisions. Many individuals and communities remain unaware of HIV self-testing, partly due to low levels of general awareness of HIV self-testing, and do not have access to HIV self-testing.*

***Product regulation, registration and selection**. Although national processes for regulation and registration of in-vitro diagnostic devices are becoming clearer in some settings, nonexistent or unclear regulatory processes are still a barrier to market entry and scale-up in both public and private sector markets in LMICs. Lack of product registration in the country where it is manufactured or assembled is also a barrier to production of free sale certificates needed for export to other countries. The processes for product selection for national programmes still largely need to be defined and streamlined in many settings.*

***Product diversity in national programmes.** While the product range available in the private sector is diverse, a single product dominates the donor-funded public sector in LMICs. This is in part due to donor and government policies that require WHO prequalification for programmatic implementation or at least, where self-tests are procured for operational research, ERPD recommendation. This requirement ensures product quality but largely limits countries' and consumers' choices, as well as leading to market dominance by a single supplier and product, the only WHO prequalified oral fluid-based self-test. Several blood-based self-test products are under assessment for WHO prequalification. Future prequalification of these products may change the situation and help diversify the product range in donor-funded programmes.*

***Ongoing donor investment and funding.** Donors have continued to fund HIV self-testing programmes and scaled up investments in 2018 to approximately US$ 9.5 – 16.6 million. To continue this scale-up, resources to cover the unfunded HIV self-test forecast volumes for 2019, 2020 and beyond need to be identified. With the STAR Initiative coming to a close for some of the project countries in late 2019, efforts to address funding gaps for self-testing scale-up need to be prioritised. While there has been progress with a strong 2018 procurement plan from donors and a strong pipeline of products, current funding has yet to translate into significant product improvement and innovation.*

***Product optimization and innovation.** HIV self-testing products in the pipeline appear to be similar to currently available products in terms of major product characteristics, with indication of only minor innovations. For example, one of the products under development would use a urine specimen. For another product in the pipeline, a version is under development that could enable users to collect and use either fingerstick/whole blood or oral fluid specimens on the same self-test device. To ease sample collection and transfer, another manufacturer removed the capillary tube/pipette and validated a hanging drop specimen transfer. There are some advances in support tools to enable users to correctly interpret their self-test results; however, these have yet to be fully adopted or implemented. Opportunities for innovation and product optimization exist to improve performance and reduce user errors as well as to use technology to facilitate linkage to onward services and monitoring.*

Barriers

A number of key barriers to the growth of the HIV self-test market remain. First, the donor-funded market is dominated by a single product, limiting choice for consumers as well as reducing market competition and supply security. Second, nonexistent, time-consuming or unclear national registration and regulatory processes for IVDs make it difficult to introduce and scale up HIV self-testing in both public and private sector markets. In some settings multiple agencies have overlapping mandates, while in others there is a complete absence of any authority to regulate IVDs. As a result, registration processes can be lengthy and expensive or may fail to prevent substandard products from entering the market. Third, lack of policies and/or product registration in the country where the test kit is manufactured or assembled is also a barrier, as certificates of free sale are needed to export and import self-tests in many countries. Finally, awareness of HIV self-testing remains low in target populations in many settings. Large-scale promotion campaigns will be needed to generate demand and facilitate market growth.

Market opportunities

The HIV self-test procurement forecast anticipates steady growth in volumes through 2020. Such growth is expected to continue beyond 2020, as some countries implement HIV self-testing for the first time and others scale up existing programmes. Limited HIV self-test procurement to date in several high-burden countries and the fact that HIV self-tests currently make up a small proportion of the total RDT market also represent major opportunities for market growth and public health impact if implementation of self-testing is prioritized in such settings.

The HIV self-test procurement forecast anticipates steady growth in volumes through 2020. Such growth is expected to continue beyond 2020, as some countries implement HIV self-testing for the first time and others scale up existing programmes.

Over the past two years, HIV self-test kits have become formally available in the private sector in several LMIC settings. Although the private sector market is nascent in LMICs, and regulatory processes are evolving, there are opportunities for prospective market entrants. Manufacturers are increasingly looking to develop partnerships with in-country distributors and organisations that have experience in local regulatory and approval processes. Such partnerships could reduce logistical challenges in product registration and supply chain processes.

They also could make expansion to new markets in additional countries more efficient. Additional opportunities for market growth will arise with the introduction and scale-up of new HIV self-testing distribution channels, such as workplace programmes and medical insurance schemes.

Further market growth opportunities are expected to emerge with a broader market for self-testing and self-sampling technologies supported by innovation in product design and manufacturing process. The momentum in HIV self-testing implementation and increasing clarity in regulatory pathways for IVDs could be leveraged to catalyze a broader market for self-testing technologies. Further optimization and automation of existing product lines could help meet likely increases in demand for self-tests and reduce the cost of manufacturing kits.

Conclusions and recommendations

In 2016, WHO recommended HIV self-testing as an additional testing approach to complement existing services. HIV self-testing is now an important strategy for closing gaps in HIV diagnosis. As of June 2018, 59 countries had adopted policies supporting HIV self-testing. Another 53 countries report having policies under development, many to be completed in 2018. Implementation of HIV self-testing programmes is underway in 28 countries, however, two-thirds of them are upper middle or high-income countries. Further evidence on the cost and cost-effectiveness of HIV self-testing and national-level investment cases will be needed to inform government and donor decisions and help countries move forward with national implementation and scale-up.

HIV self-test procurement volumes first exceeded 1 million tests annually in 2017. Global volumes are forecast to grow to 16.4 million (12.9 million – 19.3 million) by the end of 2020. The public sector is projected to contribute 9.1 million (6.3 million – 11.2 million), while the private sector is projected to contribute 7.3 million (6.6 million – 8.0 million) self-test volumes in 2020. The immediate growth in the public sector comes largely from confirmed procurement of HIV self-tests by donors including Unitaid and PEPFAR in five countries – Kenya, Malawi, South Africa, Zambia and Zimbabwe. From 2019 onwards, as additional countries implement and scale up HIV self-testing, the market is expected to grow and diversify, with 46% (4.2 million) of the total 9.1 million public sector tests in 2020 to be procured by other LMICs. In the public sector forecast estimates, 39% of volumes in 2019 (2.7 million tests) are unfunded (that is, no known resources are currently committed to their procurement). This number increases to 74% in 2020, representing a funding gap of approximately US$ 13.5 – $ 23.5 million in 2020. As for the near-term private sector forecast, the Region of Americas dominates, with 24% of total forecast volumes in 2019, along with the European Region, with 27% of total forecast volumes in 2019. Beyond 2019 growth in more densely populated markets in the South-East Asia and the Western Pacific region is expected to drive the market, with 40% of total forecast volumes in 2020.

The HIV self-testing procurement forecast predicts significant market growth in both public and private sector markets up to and beyond 2020.

A number of different HIV self-test kits have become available for procurement through donor funding in LMICs as well as in the private sector in high-income countries. Necessary national-level regulatory processes for countries importing or exporting HIV self-test kits are lengthy, unclear or absent in some settings, which acts as a barrier to implementation and scale-up. Still, the HIV self-testing procurement forecast predicts significant market growth in both public and private sector markets up to and beyond 2020, largely driven by new countries implementing HIV self-testing for the first time and scale up in countries that have already started implementation. Current momentum in the growth of the HIV self-test market, supported by ongoing innovation, can be leveraged to develop a broader market for self-testing technologies, including self-testing for diseases other than HIV.

To realize the full potential and public health impact of HIV self-testing, this report recommends a call to action in six priority areas for all stakeholders involved:

- Expedited WHO prequalification of additional HIV self-testing products to diversify the available product range and suppliers for donor-funded programmes. This should be supported by streamlining national regulatory and registration pathways and processes for product selection;
- Evidence generation and development of national-level investment cases for HIV self-testing to show the public health impact. Such evidence would encourage faster implementation.
- Establish and harmonize strategies to make HIV self-testing products more affordable to consumers (including individual users, governments and donors) at price points that achieve cost-effectiveness and investment cases demonstrate public health impact.
- Increase awareness and demand for HIV self-testing through strategic health promotion and demand generation activities that cover various innovative self-test service delivery models across the public and private sector.
- Establish and leverage strategic partnerships between manufacturers of HIV self-tests and local companies and distributors to reduce manufacturers' risk and facilitate entry into new and emerging markets.
- Prioritize and continue product optimization and innovations for existing self-tests as well as exploring opportunities to expand the use and adaptation of self-testing products for other conditions and disease areas and, thus, establish a broader market for self-testing.

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Annexes

Annex 1. HIV self-test procurement forecast methodology and assumptions

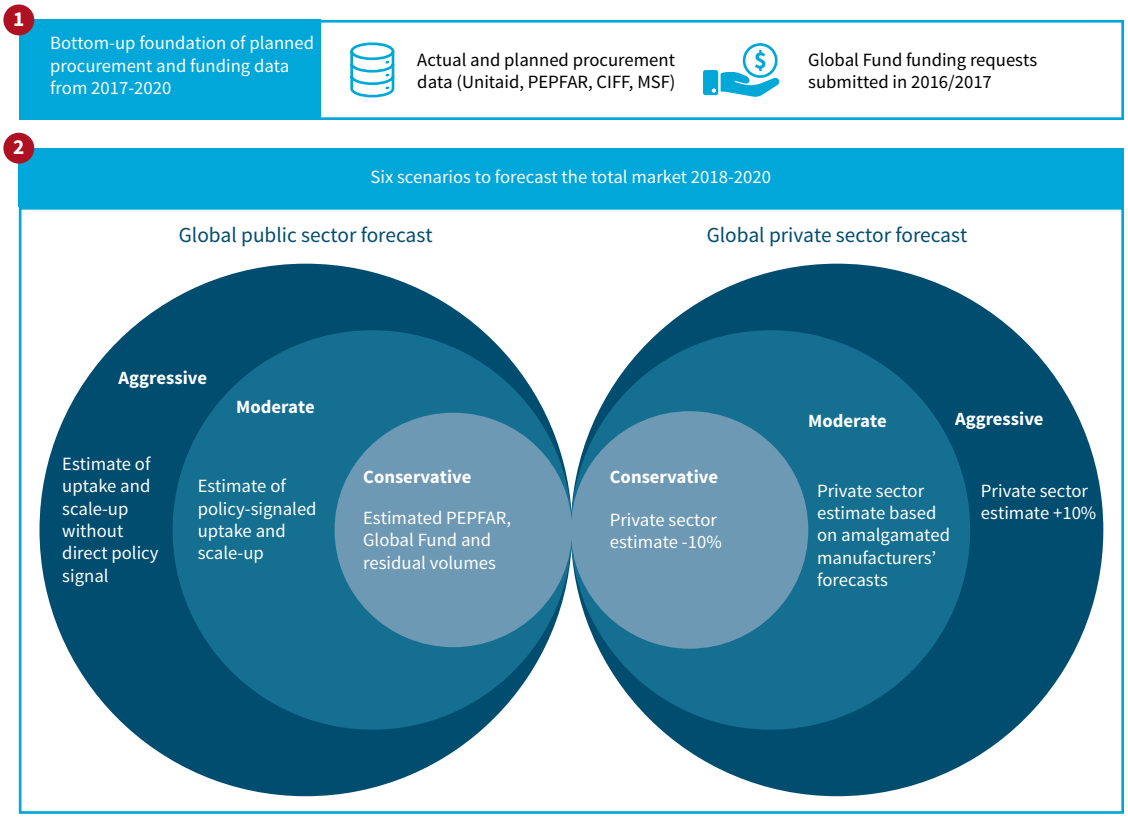
The global HIV self-test forecast consists of two market sectors (public and private), each with three scenarios (conservative, moderate and aggressive) (Fig. A1.1). The public sector forecast includes volumes for LMICs only, while the private sector forecast consists of high- and middle-income countries only. Within the public sector, each scenario is generated based on a number of cumulative estimates. The private sector forecast consists of only one estimate. The full list of estimates per scenario for the public sector forecast appears in Annex 2. Details of the private sector forecast appear in Annex 4.

Data sources and forecast scenarios

Data on actual and planned donor procurement volumes and funding are used to generate estimated future procurement volumes by donor per country. Actual and planned public sector procurement data come predominantly from Unitaid and PEPFAR and are supplemented with an interpretation of Global Fund funding requests submitted starting in 2016 through 16 April 2018. WHO, using a combination of sources, including the Global AIDS Monitoring system, policy and regulatory tracking through HIVST.org and routine data requests and analysis through partners, collects information on country policies on HIV self-testing and the general implementation situation. The policy, policy+, scale-up and scale-up+ estimates were created from the combination of the HIV self-test procurement data and the policy and implementation information available to the WHO. An additional estimate, of private sector HIV self-testing volumes, is based on amalgamated data provided by manufacturers. The forecast scenarios were created from these estimates.

FIGURE A1.1

SUMMARY OF HIV SELF-TESTING PROCUREMENT FORECAST METHODS AND SCENARIOS



CIFF: Children's Investment Fund Foundation; **MSF:** Médecins Sans Frontières; **PEPFAR:** President's Emergency Plan for AIDS Relief; **Global Fund:** Global Fund to Fight AIDS, Tuberculosis and Malaria.

1. Conservative public sector scenario

The conservative scenario assumes that, in the five countries with the largest procurement volumes in 2018 (Kenya, Malawi, South Africa, Zambia and Zimbabwe), those volumes will be at least maintained in 2019. The volumes for 2020 will be at least equal to the conservative scenario amount from 2019. For all other LMICs included in the forecast with known planned procurement volumes in 2018, it was assumed that these volumes are at least maintained across 2019 and 2020. The conservative scenario consists of the following estimates:

- The PEPFAR-funded estimate is determined by taking into account information provided per country by PEPFAR, WHO country offices and ministries of health. It is based on historical reported volumes and intentions in PEPFAR Country Operational Plans (COPs) and country strategic planning documents.

- The Global Fund in-allocation estimate is based on Global Fund grant funding requests and updates on the status of those requests provided by the Global Fund.

- The Global Fund prioritized above allocation request (PAAR) estimate is based on a subjective assessment of the above allocation funding requests and Global Fund Technical Review Panel assessment of those funding requests.

- Other donor-funded procurement is based on self-reported procurement volumes from those donors to WHO.

- The residual estimate represents the proportion of the minimum expected HIV self-tests, as described above, for which there is currently no known funding source.

2. Moderate public sector scenario

The moderate scenario is incremental to the conservative scenario and adds an estimated amount of procurement for countries that have signalled policy uptake or active implementation. The volume estimated for those with evidence of procurement is higher than those with no known procurement activity.

The moderate scenario consists of all of the estimates that constitute the conservative scenario plus the policy estimate and the scale-up estimate. The policy and scale-up estimates represent procurement by countries that are either pilot-testing, implementing or scaling up HIV self-testing through public health services in 2019 or 2020.

- The policy estimate is calculated per country for which the HIV self-testing implementation date has been reported to WHO and where there are no known procurement volumes. The policy estimate is equal to 5% of 2-year average professional use RDT volumes for that country or 5000 tests, whichever is more.

- The scale-up estimate is calculated per country for which the HIV self-testing implementation date has been reported to WHO and there are known procurement volumes. For 2019 the scale-up estimate is equal to 2.5% of 2-year average professional use RDT volumes, 5000 tests or the conservative scenario volumes, whichever is greatest. For 2020 the scale-up estimate is equal to 5% of 2-year average professional use RDT volumes, 5000 tests or the conservative scenario volumes, whichever is greatest.

The minimum 5000 test volume assumption is based on observed trends in procurement volumes for countries at early stages of adoption; manufacturers' feedback regarding order volumes from new customers; and minimum expected volumes of testing required for pilot projects and evaluations. The assumption regarding HIV self-test volumes as a proportion of RDT volumes is conservatively based on the trends observed per country with planned or funded HIV self-test procurement for 2018.

3. Aggressive public sector scenario

The aggressive scenario is incremental to the conservative and moderate scenarios and adds an estimated amount of procurement for countries where HIV self-testing implementation is more uncertain as well as additional testing volumes in the event of more aggressive scale-up efforts.

The aggressive scenario consists of all prior estimates with the addition of the policy+ estimate and the scale-up+ estimate. The policy+ estimate represents procurement by countries that may start to pilot-test or implement HIV self-testing through the national programme in 2020. The scale-up+ estimate represents procurement by countries that may more aggressively scale up HIV self-testing.

- The policy+ estimate is calculated per country that has a plan for HIV self-testing policy uptake by 2020, but for which the HIV self-testing implementation date is unknown and for which there are no known procurement volumes. For these countries HIV self-testing procurement volumes are estimated for 2020 to equal 5% of 2-year average professional use RDT volumes or 5000 tests, whichever is higher.

- The scale up+ estimate is calculated per country for which the HIV self-testing implementation date has been reported to the WHO and where there are known procurement volumes. For 2019 the scale-up estimate is equal to 5% of 2-year average professional use RDT volumes, 5000 tests or the conservative scenario volumes, whichever is greatest. For 2020 the scale-up estimate is equal to 7.5% of 2-year average professional use RDT volumes, 5000 tests or the conservative scenario volumes, whichever is greatest.

4. Private sector forecast

The private sector forecast consists of only the private sector estimate. The private sector estimate is an amalgamation and analysis of feedback and forecasts from manufacturers on private sector sales globally.

The private sector forecast is independent and incremental to the public sector forecast, as it adds an estimated amount of private sector sales in high- and middle-income countries. These sales are expected to originate from a mix of distribution channels and distribution arrangements, including through retail stores and both online and offline direct-to-consumer channels. The private sector forecast may reflect manufacturers' expectations that they will make some sales in the public sector in high-income countries. However, the public and private forecasts are not expected to be duplicative due to substantial geographical and methodological differences.

These forecasts and methodologies can be broadly described as country-based forecasts that take into consideration an understanding of need, income and population distributions and the sales volumes of analogous products. In some cases local distributors' knowledge has informed these forecasts. WHO reviewed the amalgamated forecast data at a country level to identify abnormalities or possible outliers, including duplicative values, and to align forecast periods. This process resulted in the original data being reduced by a little more than 2 million tests, mostly to account for time periods beyond the range of this forecast. To reflect some of the uncertainty with regards to the private sector estimate and align forecast methodologies with the public sector forecast an aggressive and conservative range of +/- 10% has been added post-calculation.

5. Global forecast

The global forecast is the direct summation of the public sector forecast and the private sector forecast across each of the scenarios (conservative, moderate and aggressive).

HIV self-testing procurement forecast strengths and limitations

The public sector forecast methodology is designed to be conservative by relying primarily on a foundation of known and funded procurement. This foundation is supplemented with an understanding of the changing policy and implementation environment in order to estimate HIV self-testing uptake. This bottom-up methodology prioritizes actual data

regarding procurement, funding and policy over a more conventional top-down assessment of total HIV self-test need in order to provide an indication of the future market based on the actual market, rather than the potential market. This approach is considered appropriate due to the focus of the forecast on a relatively short period of time, in which the current funding grant and procurement cycles will likely have a significant impact. The accuracy of historical procurement based forecasting for HIV self-testing volumes will decline as the period of the forecast extends. Forecasts for HIVST volumes that look beyond 2020 should consider the increasing likelihood that procurement will eventually equal the expected need. This is particularly likely when considering that the current forecast considers only funding and procurement by Unitaid, PEPFAR, Global Fund, CIFF and MSF and does not yet take into account domestic government funding.

The moderate and aggressive scenarios within the public sector forecast rely in part on assumptions about the volume of HIVST as a proportion of total RDT volumes. Consistent and comparable RDT forecasts at a country level could not be identified for use in making these assumptions. To mitigate this, an analysis of data from various sources informed these assumptions. For further details on this analysis, refer to Annex 7.

The private sector forecast was created by amalgamating market forecasts provided by manufacturers and standardizing them to the forecast period. This methodology has limitations that increase the level of uncertainty associated with it. Therefore, the private sector forecast should be interpreted with less confidence than the public sector forecast.

In addition to these methodological biases, there are a number of subjective assumptions in the forecast that should be verified in the future as more data become available. This includes assumptions pertaining to the impact of policy and implementation signals on HIV self-testing procurement; the proportion of HIV self-test volumes to total RDT volumes; and the outcome of funding decisions and allocation by the Global Fund (particularly in relation to PAAR). Efforts are already underway to strengthen the basis for these assumptions and the rate of HIV self-testing uptake associated with them. These efforts should contribute to a more systematic process of calculating the forecast in the future.

Annex 2. Public sector forecast range by planned procurement and estimate

The public sector forecast consists of three scenarios, each of which consists of a number of estimates (Table A2.1). The estimates in each scenario are incremental to the estimates that precede them. Each estimate is based on different methodology and hence has a different level of confidence (low to very high). A higher level of confidence implies a narrow band of positive and negative variance, and a low level of confidence implies a wide band of positive and negative variance. The level of confidence detailed in the table below is subjectively assessed and takes into account the perceived likelihood that the actual volumes will match the forecast volumes.

TABLE A2.1

Public sector planned procurement and forecast estimates, by type of estimate and year

Public sector planned procurement and estimates	2018	2019	2020	Confidence
Unitaid planned procurement	2 280 000	1 400 000	270 000	Very high
Other planned procurement	20 000	–	–	Very high
PEPFAR planned procurement	1 820 000	–	–	Very high
Global Fund funded volumes	560 000	770 000	30 000	High
PEPFAR estimate	–	1 770 000	1 770 000	Moderate
Global Fund estimate	–	–	210 000	High
Global Fund PAAR estimate	70 000	360 000	90 000	Low
Residual estimate	–	1 560 000	3 960 000	Moderate
Public sector – conservative	4 740 000	5 860 000	6 330 000	
Policy estimate	–	300 000	450 000	High
Scale-up estimate	–	830 000	2 350 000	Moderate
Subtotal	–	1 130 000	2 800 000	
Public sector – moderate	4 740 000	6 990 000	9 130 000	
Policy+ estimate	–	–	770 000	Low
Scale-up+ estimate	–	990 000	1 340 000	Low
Subtotal	–	990 000	2 110 000	
Public sector – aggressive	4 740 000	7 980 000	11 240 000	

Annex 3.
List of countries considered in the public sector forecast and list of countries not considered in the forecast

A total of 99 countries that had HIV self-testing policy or procurement information were considered in the public sector forecast. Not all of these countries had public sector volumes forecast. Table A3.1 lists the countries that were considered in the public sector forecast and had forecast volumes. Table A3.2 lists the countries not considered that had more than 50 000 people living with HIV.

TABLE A3.1
Countries considered in the public sector forecast

Afghanistan	Ethiopia	Namibia
Albania	Fiji	Nepal
Algeria	Gabon	Niger
Angola	Georgia	Nigeria
Armenia	Ghana	Niue
Azerbaijan	Guatemala	Pakistan
Belarus	Guinea	Paraguay
Benin	Haiti	Peru
Bolivia (Plurinational State of)	India	Philippines
Botswana	Indonesia	Republic of Moldova
Brazil	Iran (Islamic Republic of)	Rwanda
Bulgaria	Jamaica	Senegal
Burkina Faso	Kenya	Sierra Leone
Burundi	Kiribati	Somalia
Cambodia	Kosovo	South Africa
Cameroon	Kyrgyzstan	South Sudan
Central African Republic	Lao People's Democratic Republic	Sudan
Chad	Lebanon	Suriname
China	Lesotho	Tajikistan
Colombia	Libya	United Republic of Tanzania
Congo, Dem. Rep.	Malawi	Uganda
Cook Islands	Mali	Ukraine
Côte d'Ivoire	Mauritius	Uzbekistan
Cuba	Mexico	Venezuela
Dominica	Mongolia	Vietnam
El Salvador	Morocco	Zambia
Eritrea	Mozambique	Zimbabwe
Eswatini	Myanmar	

TABLE A3.2

Countries not considered in the public sector forecast with over 50 000 people living with HIV

Country	Estimated number of people living with HIV
Argentina	120 000
Chile	61 000
Congo (Brazzaville)	91 000
Dominican Republic	67 000
Malaysia	97 000
Togo	100 000

Annex 4.
Private sector forecast by geographic and income classification

TABLE A4.1

HIV self-test private sector moderate forecast, by country income and WHO region

	2017		2018		2019		2020	
Income classification	**n**	**% of total**	**n**	**% of total**	**n**	**% of total**	**n**	**% of total**
High-income	456 000	100%	618 500	78%	882 000	27%	1 156 500	16%
Lower-middle income	-	0%	-	0%	176 000	5%	1 510 500	21%
Upper-middle income	-	0%	175 000	22%	2 203 000	68%	4 648 000	64%
Total	456 000	100%	793 500	100%	3 261 000	100%	7 315 000	100%
WHO region								
African region	-	0%	75,000	9%	260,000	8%	524,000	7%
Region of the Americas	350 000	77%	600 000	76%	1 493 000	46%	1 661 500	23%
Eastern Mediterranean Region	-	0%	-	0%	-	0%	115 000	2%
European Region	106 000	23%	112 500	14%	895 000	27%	1 380 500	19%
South-East Asia Region	-	0%	-	0%	25 000	1%	785 000	11%
Western Pacific Region	-	0%	6 000	1%	588 000	18%	2 849 000	39%
Total	456 000	100%	793 500	100%	3 261 000	100%	7 315 000	100%

Annex 5.
Proportion of conservative public sector forecast by country funding status

Table A5.1 lists the proportion of total HIV self-test public sector conservative forecast volumes from 2017 to 2020 that were funded or unfunded as at 1 May 2018. Funded volumes include planned procurements or funded volumes, as reported to WHO by donors, and donor-specific estimates. The donor-specific estimates include the PEPFAR estimate, the Global Fund estimate and the Global Fund PAAR estimate. The unfunded proportions are equivalent to the residual estimate.

TABLE A5.1
Proportion of funded and unfunded HIV self-test forecast volumes, by country and donor, 2017–2020

Countries	Funded				Unfunded residual estimate
	Other donors (CIFF, MSF)	Global Fund (including PAAR)	PEPFAR	Unitaid	
Angola	0%	100%	0%	0%	0%
Botswana	0%	0%	100%	0%	0%
Burundi	0%	0%	100%	0%	0%
Cameroon	0%	0%	100%	0%	0%
Côte d'Ivoire	0%	0%	24%	76%	0%
Congo, Dem. Rep.	26%	0%	38%	0%	37%
Eritrea	0%	100%	0%	0%	0%
Eswatini	0%	2%	81%	17%	0%
Ghana	0%	100%	0%	0%	0%
Guinea	33%	0%	0%	0%	67%
India	0%	26%	0%	0%	74%
Indonesia	0%	100%	0%	0%	0%
Kenya	2%	26%	51%	0%	22%
Lesotho	0%	0%	0%	91%	9%
Malawi	0%	14%	21%	28%	37%
Mali	0%	0%	0%	100%	0%
Mauritius	0%	100%	0%	0%	0%
Morocco	0%	89%	0%	0%	11%
Mozambique	0%	91%	9%	0%	0%
Namibia	0%	0%	100%	0%	0%
Nepal	0%	63%	0%	0%	37%
Nigeria	0%	32%	39%	0%	28%
Pakistan	0%	100%	0%	0%	0%

Countries	Funded				Unfunded residual estimate
	Other donors (CIFF, MSF)	Global Fund (including PAAR)	PEPFAR	Unitaid	
Rwanda	0%	0%	100%	0%	0%
Senegal	0%	0%	5%	95%	0%
South Africa	0%	0%	0%	56%	44%
South Sudan	0%	100%	0%	0%	0%
Uganda	0%	0%	100%	0%	0%
Ukraine	0%	26%	23%	0%	52%
United Rep. of Tanzania	0%	21%	79%	0%	0%
Viet Nam	0%	67%	0%	0%	33%
Zambia	0%	14%	32%	12%	42%
Zimbabwe	0%	3%	49%	38%	10%
Total	0%	12%	31%	26%	31%

In the table, the higher the proportion of funding attributed to a donor or the residual estimate the darker the cell highlighting.

Annex 6. HIV self-testing funding and procurement timelines

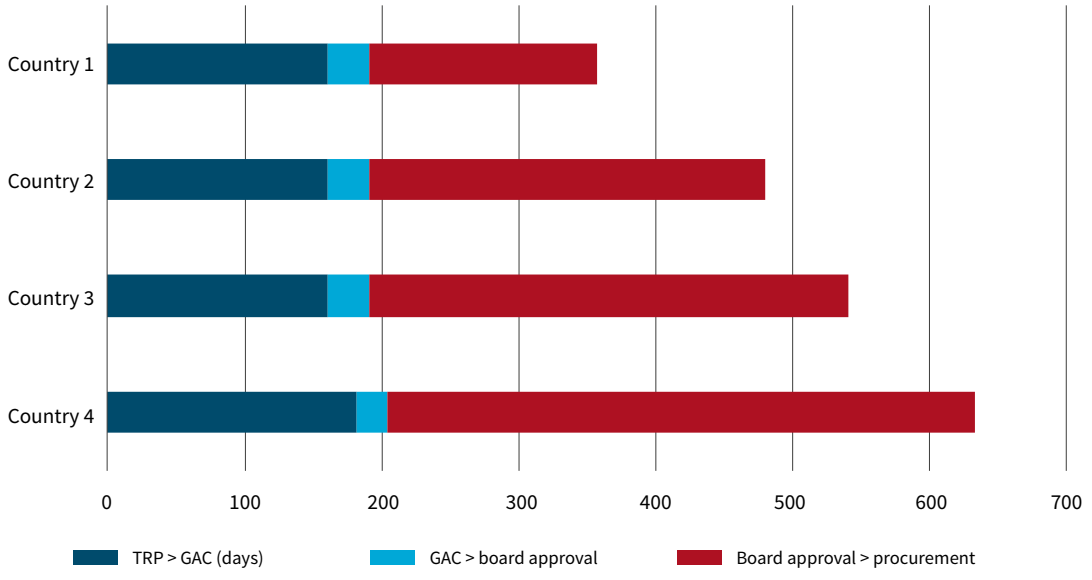
For many LMICs the process of obtaining funding and procuring HIV self-tests can be long and is likely to limit the uptake and scale-up of HIV self-test volumes prior to 2020. The following analysis of Global Fund financing timelines and PEPFAR procurement timelines provides an illustrative indication of how long the combined financing and procurement process can take. These processes are sequential and should be considered separately.

Global Fund timelines

The Global Fund funding timelines reported in Fig. A6.1 and Table A6.1 have been created based on actual HIV self-testing line items in Global Fund requests still in process as at 1 May 2018. These four countries were selected from a total of 12, as they were the only countries where the necessary information was available. The timelines reflect estimated procurement dates provided by Global Fund based on discussions with Global Fund country team members, managers and health commodity specialists. The elapsed time between the Technical Review Panel approval and the board approval is relatively consistent and depends mostly on the quality of the grant application. The elapsed time between board approval and procurement depends on a wide variety of factors, including the status of country policy adoption and implementation. Many of these factors are not under Global Fund control and depend on other stakeholders, such as the procurement agent.

FIGURE A6.1

GLOBAL FUND ILLUSTRATIVE FUNDING TIMELINES FOR HIV SELF-TEST PROCUREMENT IN PROCESS AS AT 1ST MAY 2018



TRP: Technical Review Panel; **GAC =** Grant Approval Committee.
For more information on the Global Fund funding process, see: https://www.theglobalfund.org/en/funding-model/funding-process-steps/

TABLE A6.1

Illustrative Global Fund timelines related to HIV self-testing grant requests, by procurement agent

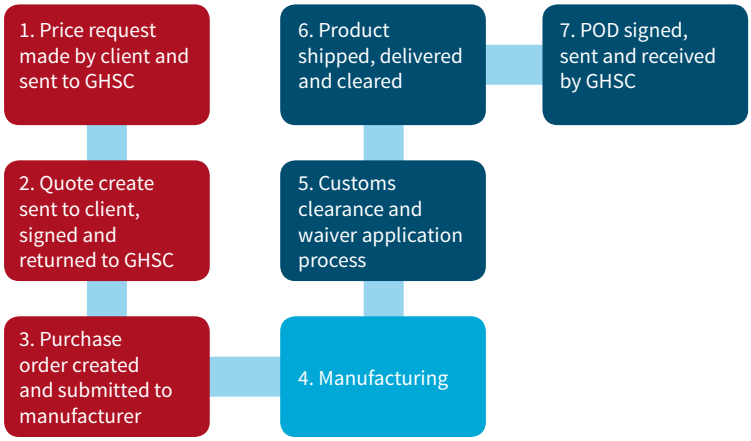
Country	TRP Date	GAC meeting date	Board approval date	Quarter year estimate for procurement	Procurement agent
Country 1	May-17	Oct-17	Dec-17	2018 Q2	Local
Country 2	May-17	Oct-17	Dec-17	2018 Q3	International
Country 3	May-17	Oct-17	Dec-17	2018 Q4	Local
Country 4	May-17	Nov-17	Dec-17	2019 Q1	Global Fund Pooled Procurement Mechanism (PPM)

Global Health Supply Chain procurement timelines

Global Health Supply Chain–Rapid Test Kits (GHSC-RTK) is the main procuring agent for PEPFAR and USAID purchases of RDTs including HIV self-tests. Clients, GHSC–RTK and manufacturers take seven consolidated steps to order, manufacture and deliver RDTs for professional use or self-testing (Fig. 16). The steps in blue *(1–3)* in Fig. A6.2 relate to the order processing days, while the orange step *(4)* relates to the manufacturing days, and the grey steps *(5-7)* relate to the waiver processing, shipping and delivery days.

FIGURE A6.2

FLOW-CHART OF HIV RAPID DIAGNOSTIC TESTS INCLUDING HIV SELF-TEST PROCUREMENT THROUGH THE GLOBAL HEALTH SUPPLY CHAIN



POD: proof of delivery

In understanding the elapsed time for procurement, it is important to note that the manufacturing period can overlap with waiver processing periods, and waiver processing time is sometimes reported as delivery time. However, the total elapsed time is reliable and should be included in procurement and supply management plans (Peter Smith, Global Health Supply Chain, personal communication 20 April 2018). Most extended waiver processing and delivery timelines are a result of complications with customs processing and should be included in delivery planning timelines based on individual conversations with customers in countries where it may be a problem.

In terms of appropriate planning at country, donor and manufacturer levels for RDT procurement, the following additional points should be considered:

- The average quote processing period beginning from price request received from the GHSC to quote signed and returned by the client is 39 days. Country-based procurement teams should keep this in mind when conducting forecasting and quantification exercises.

- On average, it takes 13 days to turn a signed quote into a purchase order and submit it to a manufacturer.

- The estimated average manufacturing time required is 21 days, but this depends on the size of the order. Typically, due to low volumes and small orders, HIV self-testing products are manufactured on-demand when a purchase order is received, which is in contrast to professional-use RDTs, which typically are made according to production schedules.

- Customs clearance and waiver processing takes 31 days on average, but it can cause significant delays if complications arise. Having all necessary registrations and product approval documentation in place and frequent communication are key to ensuring a smooth process. The GHSC typically will not release goods for shipping unless all reasonable precautions have been taken to ensure smooth product clearance at the dock.

- From the date of waiver receipt to delivery usually takes 28 days, with an additional 5 days on average required for proof of delivery to be obtained.

Annex 7.
HIV self-test volumes as a proportion of total rapid diagnostic test volumes

The proportion of HIV self-tests to total RDT volumes varies by the source of data and the denominator used for total RDT volumes. Therefore, a number of scenarios using a variety of data have been used to inform the forecast assumptions and conduct sensitivity analysis. The data sources used for calculating HIV self-tests as a proportion of total RDT volumes are presented in Tables A7.1–4. Related results are presented in Figs. A7.1 and A7.2.

TABLE A7.1.
Data sources, numerator and denominators used for calculations

	Numerator	Denominator
Global comparison	WHO Global moderate forecast total volume per year	Avenir Health global RDT forecast total RDT volumes for the relevant year
Global comparison (excluding China)	WHO Global moderate forecast total volume per year	Avenir Health global RDT forecast total RDT volume less China volumes
Public sector comparison	WHO HIVST public sector moderate forecast total volume per year	Total 2-year (2016/17) average RDT volumes reported to WHO[b]
5 key country comparison[a]	Sum of the WHO HIVST public sector moderate forecast volumes for the five key countries per year	Sum of 2-year (2016/17) average RDT volumes reported to WHO[b] for the five key countries
All other LMICs comparison	WHO HIVST public sector moderate forecast total volume less the volumes for the five key countries per year	Total 2-year (2016/17) average RDT volumes reported to WHO[b] less the volumes for the five key countries
Individual country analysis	WHO HIVST public sector moderate forecast volumes for the five key countries each per year	The 2-year (2016/17) average RDT volumes reported to WHO[b] for the five key countries each

[a] Kenya, Malawi, South Africa, Zambia and Zimbabwe
[b] WHO survey data were not available for South Africa, therefore 2016/17 average PEPFAR RDT volumes were used instead.

HIVST: HIV self-test

TABLE A7.2.
Avenir Health global rapid diagnostic test market forecast values

	2017	2018	2019	2020
Total RDT volume	333 116 934	343 826 995	353 370 930	359 509 202
Total RDT volume excluding China	183 116 934	193 826 995	203 370 930	209 509 202

As shared at AIDS Medicines and Diagnostics (AMDS), April 2018, Geneva. Note that Total RDT Volume (first row) includes an estimated 150 000 000 tests in China.

TABLE A7.3.

HIV self-test public sector moderate forecast as a proportion of total rapid diagnostic test volumes

	2017	2018	2019	2020
Global comparison	0.3%	1.6%	2.9%	4.6%
Global comparison (excluding China)	0.6%	2.9%	5.0%	7.8%
Public sector comparison	0.6%	4.2%	6.2%	8.0%
5 key countries comparison	2.3%	16.0%	18.1%	18.8%
All other LMICs comparison	0.0%	0.7%	2.6%	4.8%

TABLE A7.4.

Public sector moderate forecast as proportion of 2-year (2016/2017) average rapid diagnostic test volumes reported to WHO

	2017	2018	2019	2020	RDT volumes
Kenya	1%	21%	39%	35%	2 351 110
Malawi	5%	12%	19%	29%	2 640 840
South Africa*	2%	10%	10%	10%	12 278 120
Zambia	2%	25%	24%	24%	6 681 100
Zimbabwe	5%	21%	22%	22%	2 124 340
All other LMIC	0%	1%	3%	5%	87 601 401
Total	1%	4%	6%	8%	113 676 911

* Includes 2-year (2016/17) average PEPFAR RDT volumes for South Africa; WHO survey data were not available.

FIGURE A7.1.

HIV SELF-TESTS AS A PROPORTION OF 2016 PEPFAR RAPID DIAGNOSTIC TESTS VOLUMES, 2017–2020

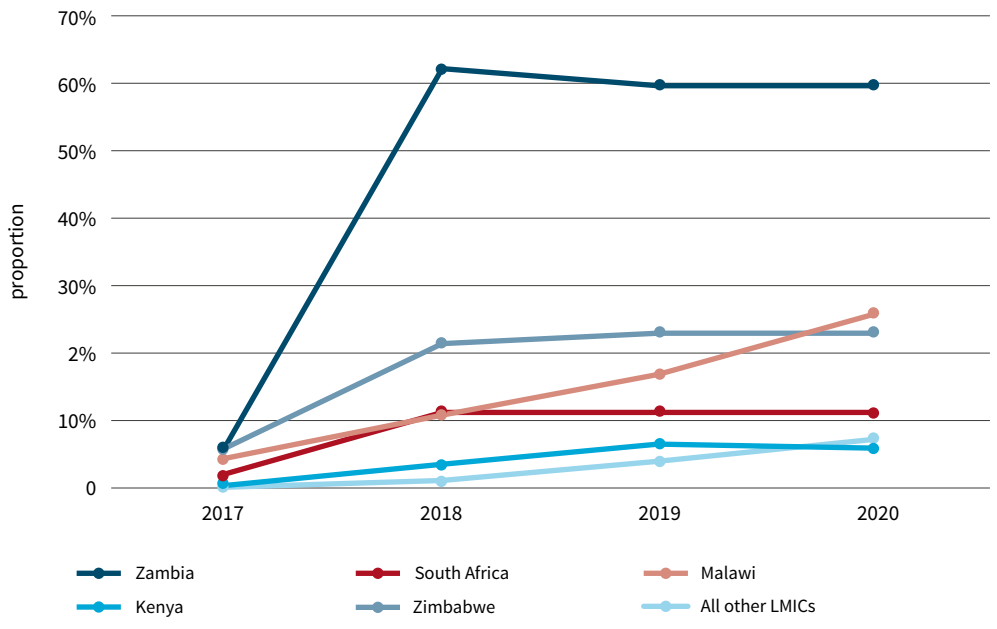
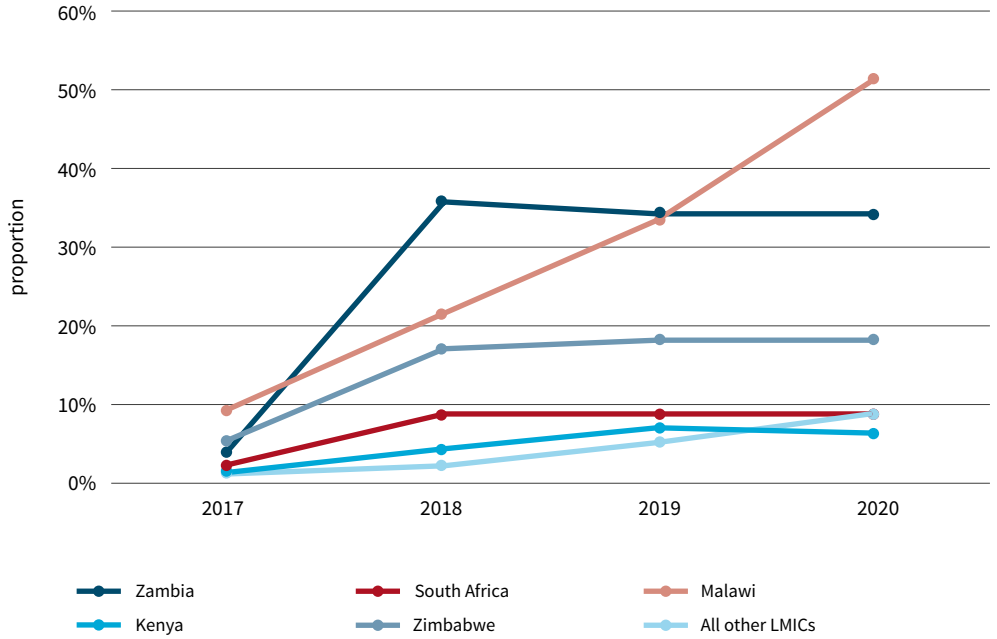


FIGURE A7.2.

HIV SELF-TESTS AS A PROPORTION OF 2017 PEPFAR RAPID DIAGNOSTIC TEST VOLUMES, 2017–2020



Annex 8.
Product specifications for HIV self-test kits prequalified by WHO, approved by a regulatory authority in one of the founding member countries of the International Medical Device Regulators Forum, or recommended by Unitaid/Global Fund Expert Review Panel for Diagnostics

The following product specification sheets include information provided by manufacturers of HIV self-test kits prequalified by WHO, approved by a regulatory authority in one of the founding member countries of the International Medical Device Regulators Forum, or recommended by the Unitaid/Global Fund Expert Review Panel for Diagnostics for procurement in LMIC settings. The information from manufacturers, including the sensitivity and specificity, reflects what is stated in manufacturers' instructions for use and what is recognized by the relevant regulatory authority. HIV self-test generation was reviewed by WHO prequalification against their records, where available. The manufacturers reviewed information on their products before publication.

atomo HIV Self Test

Product specification	
Manufacturer	Atomo Diagnostics
Manufacturing site	Australia
Professional test basis (commercial professional-use name – trademark)	AtomoRapid™ HIV (1&2)
Approval status for professional-use product	CE mark
HIV-self test product information	
Commercial name (trademark)	atomo HIV Self Test
Product photo	

atomo HIV Self Test (continued)	
Type of technology	Immunochromatography (lateral flow)
Test generation	3rd
Antigen type	Recombinant proteins for HIV-1 and HIV-2
Output	Qualitative immunoassay, HIV-1/2 antibody detection
Controls	Test has internal control (control line) to indicate sample has migrated. Control specimens (for example, test kit controls) are available but sold separately.
Sensitivity	99.7%
Specificity	99.7%
Invalid rate	0.1%
Sample type	Whole blood
Capacity	Single specimen – one-time use
Volume of sample required	10 µL
Volume of buffer required	90–120 µL
Time to result	Do not read before 15 minutes
Read window	Do not read after 20 minutes
Protocol complexity – steps required	1. Pull green tab to remove lancet cap and push grey button firmly to prick finger. 2. Squeeze finger firmly to extract blood and touch blood to tip of blood tube and fill tube. 3. Flip blood tube over to the well. 4. Add 4 drops of buffer solution. 5. Interpret test result.

atomo HIV Self Test (continued)	
Shelf life of test kit	24 months
Storage requirements	Store between 2–30 C°; do not store in direct sunlight
Test kit components	Box containing integrated test device, buffer solution, instructions for use, disposal bag and care card for linkage to care.
Not included in test kit	Timer
Restrictions for use	Not suitable for people taking ART. Not suitable for people already diagnosed as HIV-positive. Not suitable for blood donors or people with blood clotting or bleeding disorders (for example, haemophilia).
Approval status	CE mark National regulatory approval for sale in Kenya Plan to pursue WHO prequalification Recommended by Unitaid/Global Fund Expert Review Panel for Diagnostics (category-3)
Countries where registered and available	Kenya, South Africa (marketed as i-test HIV Self Test in South Africa)
Instructions for use languages available	English, Kiswahili, Zulu
Pricing (US$ per test)	$3, depends on volume for public sector
Sale mechanism (directly to consumers/ intermediary marketing/both)	Both
Minimum order size for intermediary marketing	5000 units
Additional details	People taking ARV drugs for prevention (PrEP) have formally evaluated the test kits, although the current product does not make an intended use claim for people on PrEP. www.atomohivtest.com

autotest VIH®

Product specification	
Manufacturer	AAZ-LMB
Manufacturing site	Boulogne-Billancourt, France
Professional test basis (commercial professional-use name – trademark)	SURE CHECK® HIV-1/2, STAT-VIEW® HIV-1/2 Assay
Approvals for professional-use product	CE mark, FDA, WHO prequalification
HIV-self test product information	
Commercial name (trademark)	autotest VIH®
Product photo (three packaging formats)	
Type of technology	Immunochromatography (lateral flow)
Test generation	2nd
Antigen type	Synthetic: gp36, gp41, gp120; control line: Protein A
Output	Qualitative immunoassay, HIV-1/2 antibody detection
Controls	Test has an internal control (in the control line) to indicate that human specimen has been added and that it has well migrated (no false-negative risk). Control specimens (for example, test kit controls) are available but sold separately.
Sensitivity	100%
Specificity	99.8%
Invalid rate	0.8%
Sample type	Whole blood
Capacity	Single specimen – one-time use
Volume of sample required	2.5 µL (integrated blood sampling system)
Volume of buffer required	150–200 µL (350 µL pre-measured enclosed in sealed buffer pot included)
Time to result	Do not read before 15 minutes
Read window	Do not read after 20 minutes

autotest VIH® (continued)	
Protocol complexity – steps required	1. Set up the stand and buffer. 2. Remove cap from safety lancet and apply to finger. 3. Collect sample by placing end of barrel onto drop of blood to naturally collect sample. 4. Insert tip of test device into the buffer pot by pushing device tip through foil lid to the bottom of the pot. 5. Interpret test result.
Shelf life of test kit	24 months
Storage requirements	8–30 C°. Do not store in direct sunlight.
Test kit components	1 foil pouch containing test device, buffer cap, desiccant packet, bandage, safety lancet, test stand, disinfectant wipe, sterile pad and instructions for use.
Not included in test kit	Timer
Restrictions for use	Wash hands and ensure they are clean and dry before testing. Do not use beyond expiration date. Do not open pouch until ready to perform test. Not intended for individuals with HIV-1 or HIV-2 who are on ART.
Approval status	CE mark
Countries where registered and available	Registered and available in 15 European countries
Instructions for use languages available	Bambara, Chinese, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Haitian Creole, Hungarian, Italian, Lingala, Norwegian, Polish, Portuguese, Romanian, Russian, Slovenian, Spanish, Swahili, Swedish, Wolof.
Pricing (US$ per test)	US$ 20–28 recommended consumer price in Europe; US$ 8–15 for distributors and NGOs depending on packaging format
Sale mechanism (directly to consumers/ intermediary marketing/both)	Both
Minimum order size for intermediary marketing	Varies according to packaging and instructions for use requirements, pricing and other factors, but generally 1000 units
Additional details	People using ARV drugs for treatment and for prevention (for example, PrEP or PEP) have formally evaluated the test kit; however, the current product does not make an intended use claim for people on PrEP or PEP. www.autotest-vih.eu; www.autotest-sante.com

BioSURE HIV Self Test (hardcase/softcase)

Product specification	
Manufacturer	BioSURE United Kingdom, Ltd.
Manufacturing site	United Kingdom
Professional test basis	SURE CHECK® HIV-1/2/STAT-VIEW® HIV-1/2
Approvals for professional-use product	CE mark Currently undergoing WHO prequalification assessment
HIV-self test product information	
Commercial name (trademark)	BioSURE HIV Self Test
Product photo (sold in two packaging formats – only one shown)	
Type of technology	Immunochromatography (lateral flow)
Test generation	2nd
Antigen type	Synthetic: gp36, gp41, gp120; control line: Protein A
Output	Qualitative immunoassay, HIV-1/2 antibody detection
Controls	Test has a control to indicate that human specimen has been added. Control specimens (for example, test-kit controls) are available but sold separately.
Sensitivity	99.7%
Specificity	99.9%
Invalid rate	0.45%
Sample type	Whole blood
Capacity	Single specimen – one-time use
Volume of sample required	2.5 µL (Integrated blood sampling system)
Volume of buffer required	150–200 µL (350 mL pre-measured enclosed in sealed buffer pot included)
Time to result	Do not read before 15 minutes
Read window	Do not read after 60 minutes

BioSURE HIV Self Test (hardcase/softcase) (continued)	
Protocol complexity – steps required	1. Set up stand and buffer. 2. Remove cap from safety lancet and apply to finger. 3. Collect sample by placing end of barrel onto drop of blood to naturally collect sample. 4. Insert tip of test device into the buffer pot by pushing device tip through foil lid to the bottom of the pot. 5. Interpret test result.
Shelf life of test kit	24 months after manufacture
Storage requirements	8–30 C° – do not store in direct sunlight
Test kit components	A carton or paper-based box including 1 foil pouch (containing test device, safety lancet, bandage), instructions for use booklet, integrated results reading booklet, disposal bag and product insert.
Not included in test kit	Timer
Restrictions for use	Wash hands and ensure they are clean and dry before testing. Do not open pouch until ready to perform test. Do not use beyond expiration date. Not intended for individuals with HIV-1 or HIV-2 who are on antiretroviral therapy.
Approval status	CE mark Recommended by Unitaid/Global Fund Expert Review Panel for Diagnostics (category-3)
Countries where registered and available	South Africa, United Kingdom
Instructions for use languages available	Not available
Pricing (US$ per test)	United Kingdom: US$ 42–48 recommended retail price (including tax) for direct-to-consumer sales via e-commerce and private-sector pharmacies. South Africa: US$ 11.75 (R159) recommended retail price (including tax) for direct-to-consumer sales via e-commerce and private-sector pharmacies. US$ 7.50–15 for sale to the public sector, including United Kingdom NGOs and United Kingdom National Health Service
Sale mechanism (directly to consumers/ intermediary marketing/both)	Both
Minimum order size for intermediary marketing	None
Additional details	Test kit has not been evaluated formally among people using ARV drugs for prevention (for example, PrEP or PEP). https://hivselftest.co.uk

Exacto® Test HIV

Product specification	
Manufacturer	Biosynex Group
Manufacturing site	France
Professional test basis (commercial professional-use name – trademark)	Exacto® Pro Test HIV
Approvals for professional-use product	CE mark
HIV-self test product information	
Commercial name (trademark)	Exacto® Test HIV
Product photo	
Type of technology	Immunochromatography (lateral flow)
Test generation	3rd
Antigen type	Recombinant antigen as labelled conjugate. Synthetic: gp41, gp36
Output	Qualitative immunoassay, HIV-1/2 antibody detection
Controls	There are two controls on the cassette test, the first is that the square “blood” must be red before adding the diluent. The second control line “C” confirms that the specimen migrated correctly. Control specimens (for example, test-kit controls) are available but sold separately.
Sensitivity	99.99%
Specificity	99.90%
Invalid rate	Not available
Sample type	Whole blood
Capacity	Single specimen – one-time use
Volume of sample required	5 µL
Volume of buffer required	2 drops (or 80 µL)
Time to result	Do not read before 10 minutes
Read window	Do not read after 20 minutes

Exacto® Test HIV (continued)	
Protocol complexity – steps required	1. Remove lid from safety lancet and apply to finger. 2. Squeeze finger and use inverted cup/capillary tube to collect sample. 3. Add drop of blood to the test cassette where marked “blood”. 4. Add buffer to the test cassette where marked “diluent”. 5. Interpret test result.
Shelf life of test kit	24 months after release of production
Storage requirements	2–30 C°. Do not store in direct sunlight or open foil packet until ready to use test.
Test kit components	1 foil pouch with test cassette and desiccant, buffer solution, bandage, alcohol wipe, sterile pad, lancet, inverted cup/capillary tube, instructions for use, disposal bag.
Not included in test kit	Timer
Restrictions for use	Wash hands and ensure they are clean and dry before testing. Test must be run immediately after the capillary blood has been collected. Not intended for individuals with HIV-1 or HIV-2 who are on ART. Test should be run in a setting at 15–30 C°.
Approval status	CE mark
Countries where registered and available	Europe (countries not available)
Instructions for use languages available	English, Dutch, French, German, Italian, Portuguese, Spanish. Local African languages for field studies: Lingala, Sango, Swahili.
Pricing (US$ per test)	To be determined
Sale mechanism (directly to consumers/ intermediary marketing/both)	Both
Minimum order size for intermediary marketing	To be determined
Additional details	Test kit has not been evaluated formally among people using ARV drugs for prevention (for example, PrEP or PEP).

INSTI® HIV Self Test (box/pouch)

Product specification	
Manufacturer	bioLytical Laboratories
Manufacturing site	Richmond, British Columbia, Canada
Approval status for professional-use product	CE mark/FDA/Health Canada/WHO prequalification
Professional test basis (commercial professional-use name – trademark)	INSTI® HIV-1/HIV-2 Antibody Test
HIV-self test product information	
Commercial name (trademark)	INSTI® HIV Self Test
Product photo (sold in two packaging formats)	
Type of technology	Immunofiltration (flow through)
Test generation	2nd
Antigen type	gp41 and gp36 antigen; control: Protein A
Output	Qualitative immunoassay, HIV-1/2 combined antibody detection
Controls	Built-in procedural control of Protein A, which detects the human IgG antibodies. Test kit quality controls available upon request.
Sensitivity	100%
Specificity	99.8%
Invalid rate	Not available
Sample type	Whole blood
Capacity	Single specimen – one-time use
Volume of sample required	50 µL
Volume of buffer required	1.5mL sample diluent, 1.5 mL colour developer, and 1.5 mL of clarifying solution
Time to result	Instant results after completion of procedure
Read window	Do not read after 1 hour

INSTI® HIV Self Test (box/pouch) (continued)	
Protocol complexity – steps required	1. Remove cap of sample diluent. 2. Remove lid from safety lancet and apply to finger. 3. Collect sample (finger prick). 4. Insert sample into sample diluent. 5. Sequentially invert and pour sample diluent, colour developer and clarifying solution onto test device. 6. Interpret test result.
Shelf life of test kit	15 months
Storage requirements	Store at 2–30 C°
Test kit components	1 cardboard box/pouch containing test device, sample diluent, colour developer, clarifying solution, instructions for use and/or booklet, 1 sterile single-use lancet and an adhesive bandage.
Not included in test kit	Not available
Restrictions for use	Not suitable for users who have a bleeding disorder. Not suitable for users below the age of 18 years. Not suitable for users who are taking ARV drugs for prevention (for example, PrEP or PEP) or treatment (that is, ART). Not suitable for users who have participated in an HIV vaccine study.
Approval status	CE mark Recommended by Unitaid/Global Fund Expert Review Panel for Diagnostics (category-3)
Countries where registered and available	Austria, Belgium, France, Kenya, Italy, Luxembourg, Netherlands, Nigeria, Portugal, Spain, Switzerland, United Kingdom
Instructions for use languages available	Dutch, English, French, German, Italian, Kiswahili, Portuguese, Spanish
Pricing (US$ per test)	US$ 3 to US$ 12 depending on packaging format, volumes and market region. Maximum suggested retail price: US$ 7 to US$ 36, depending on packaging format and market region.
Sale mechanism (directly to consumers/ intermediary marketing/both)	Both
Minimum order size for intermediary marketing	Box: No minimum order size for intermediary marketing Pouch: 4000
Additional details	The test has not been formally tested among people who are on ART either for treatment of infection or in PrEP programmes. www.insti.com

OraQuick® In-Home HIV Test

Product specification	
Manufacturer	OraSure Technologies, Inc.
Manufacturing site	Bethlehem, Pennsylvania, United States of America
Professional test basis (commercial professional-use name – trademark)	OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test
Approvals for professional-use product	FDA, CE mark
HIV-self test product information	
Commercial name (trademark)	OraQuick® In-Home HIV Test
Product photo	
Type of technology	Immunochromatography (lateral flow)
Test generation	2nd
Antigen type	Synthetic peptides representing the HIV envelope region and a goat anti-human IgG procedural control immobilized onto a nitrocellulose membrane in the test (T) zone and the control (C) zone
Output	Qualitative immunoassay, HIV-1/2 antibody detection
Controls	Addition of procedural quality control (band appears when human specimen is added and sample has flowed up the device).
Sensitivity	FDA: 91.7%* CE mark: 100%
Specificity	FDA: 99.98%* CE mark: 99.8%
Invalid rate	FDA: 1.1% CE mark: 1.8%
Sample type	Oral fluid
Capacity	Single specimen – one-time use
Volume of sample required	Not applicable
Volume of buffer required	1 mL
Time to result	Do not read before 20 minutes
Read window	Do not read after 40 minutes

* US FDA approval required unobserved use testing relying on individuals to correctly report their test results without a trained professional confirming the self-reported result. Additional information available at:
https://www.fda.gov/biologicsbloodvaccines/bloodbloodproducts/approvedproducts/premarketapprovalspmas/ucm310436.htm

OraQuick® In-Home HIV Test (continued)	
Protocol complexity – steps required	1. Remove cap of developer solution. 2. Set buffer vial in stand. 3. Collect sample (oral swab). 4. Insert sample in buffer vial. 5. Interpret test result.
Shelf life of test kit	30 months
Storage requirements	Store at 2–30 C° – do not open foil packet until ready to use test.
Test kit components	Plastic package encasing a divided pouch (containing test device, desiccant, developer solution vial), test/buffer stand, pencil, disposal bag, instructions for use and informational booklets about HIV.
Not included in test kit	Timer
Restrictions for use	Do not eat, drink or chew gum for at least 15 minutes before testing or use mouth cleaning products 30 minutes before taking the test. Do not open pouch until ready to perform test. Not intended for individuals with HIV-1 or HIV-2 who are on ART. Not for use in individuals less than 17 years old. Operate at 15–37 C°.
Approval status	FDA CE mark
Countries where registered and available	United States
Instructions for use languages available	English, Spanish
Pricing (US$ per test)	US$ 40 recommended consumer price in the US; prices for public sector may vary. Recommended prices outside the US not yet available.
Sale mechanism (directly to consumers/ intermediary marketing/both)	Both
Minimum order size for intermediary marketing	No standard minimum order size; tests are shipped in units of six tests.
Additional details	Test kit has not been evaluated formally among people using ARV drugs for prevention (for example, PrEP or PEP). http://www.oraquick.com

OraQuick® HIV Self-Test

Product specification	
Manufacturer	OraSure Technologies, Inc.
Manufacturing site	USA – assembled in Thailand
Professional test basis (commercial professional-use name – trademark)	OraQuick® Rapid HIV-1/2 Antibody Test
Approvals for professional-use product	WHO prequalification
HIV-self test product information	
Commercial name (trademark)	OraQuick® HIV Self-Test
Product photo (sold in two packaging formats)	 Pharmacy version  Community version
Type of technology	Immunochromatography (lateral flow)
Test generation	Not available*
Antigen type	Synthetic peptides representing the HIV envelope region and a goat anti-human IgG procedural control immobilized onto a nitrocellulose membrane in the test (T) zone and the control (C) zone.
Output	Qualitative immunoassay, HIV-1/2 antibody detection
Controls	Test has a control to indicate that human specimen has been added (that is, band appears when human specimen is added).
Sensitivity	99.4%
Specificity	99.0%
Invalid rate	1.8%
Sample type	Oral fluid
Capacity	Single specimen – one-time use
Volume of sample required	Not applicable
Volume of buffer required	1 mL
Time to result	Do not read before 20 minutes
Read window	Do not read after 40 minutes

* Pending WHO prequalification review of change notification

OraQuick® HIV Self-Test (continued)	
Protocol complexity – steps required	1. Remove cap of developer solution. 2. Set buffer vial in stand. 3. Collect sample (oral swab). 4. Insert sample in buffer vial. 5. Interpret test result.
Shelf life of test kit	30 months
Storage requirements	Store at 2–30 C°
Test kit components	Plastic package encasing a divided pouch (containing test cassette, desiccant, vial of buffer), test/buffer stand and instructions for use
Not included in test kit	Timer
Restrictions for use	Do not eat, drink or chew gum for at least 15 minutes before testing or use mouth cleaning products 30 minutes before taking the test. Do not use beyond expiration date. Do not open pouch until ready to perform test. Not intended for individuals with HIV-1 or HIV-2 who are on ARV. Not for use in individuals less than 12 years old. Operate at 15–37 C°.
Approval status	WHO prequalification
Countries where registered and available	Burundi, Kenya, South Africa, Uganda, Zambia, Zimbabwe
Instructions for use languages available	Available in English, French, Mandarin, Portuguese, Russian, Spanish and 40 additional languages. www.oraquickhivselftest.com
Pricing (US$ per test)	US$ 2 for 50 low- and middle-income countries (pursuant to agreement with Bill & Melinda Gates Foundation) http://www.orasure.com/products-infectious/products-infectious-oraquick-self-test.asp
Sale mechanism (directly to consumers/ intermediary marketing/both)	Both
Minimum order size for intermediary marketing	No standard minimum order size; tests are shipped in units of 50 or 250 tests.
Additional details	Test kit has not been evaluated formally among people using ARV drugs for prevention (for example, PrEP or PEP). www.oraquickhivselftest.com

SURE CHECK® HIV Self Test

Product specification	
Manufacturer	Chembio Diagnostic Systems, Inc.
Manufacturing site	Medford, New York, United States of America
Professional test basis (commercial professional use name – trademark)	SURE CHECK® HIV-1/2
Approvals for professional use product	WHO prequalification, CE mark, FDA
HIV-self test product information	
Commercial name (trademark)	SURE CHECK® HIV Self Test
Product photo	
Type of technology	Immunochromatographic (lateral flow)
Test generation	2nd
Antigen type	Synthetic: gp36, gp41, gp120; control line: Protein A
Output	Qualitative immunoassay, HIV-1/2 antibody detection
Controls	Test has a control to indicate that human specimen has been added. Control specimens (for example, test kit controls) are available but are sold separately.
Sensitivity	Not available
Specificity	Not available
Invalid rate	Not available
Sample type	Whole blood
Capacity	Single specimen – one-time use
Volume of sample required	2.5 µL (integrated blood sampling system)
Volume of buffer required	150-200µL (350 mL pre-measured enclosed in sealed buffer pot included)
Time to result	Do not read until 15 minutes
Read window	Do not read after 20 minutes

SURE CHECK® HIV Self Test (continued)	
Protocol complexity – steps required	1. Set-up stand and buffer. 2. Remove cap from safety lancet and apply to finger. 3. Collect sample by placing end of barrel onto drop of blood to naturally collect sample. 4. Insert tip of test device into the buffer pot by pushing device tip through foil lid to the bottom of the pot. 5. Interpret test result.
Shelf life of test kit	24 months
Storage requirements	Store at 8–30 C°. Do not store in direct sunlight or open foil packet until ready to use test.
Test kit components	Test stand, sterile gauze pad, disinfectant wipe, and 1 foil pouch containing test device, buffer cap, desiccant packet, bandage and safety lancet, instructions for use.
Not included in test kit	Timer
Restrictions for use	Wash hands and ensure they are clean and dry before testing. Do not open pouch until ready to perform test. Not intended for individuals with HIV-1 or HIV-2 who are on ART. Do not reuse the test.
Approval status	Recommended by Unitaid/Global Fund Expert Review Panel for Diagnostics (category-3) The manufacturer plans to pursue WHO prequalification Two private-label versions of the product are CE-marked for self-testing in the European Union (BioSURE HIV Self-Test and autotest VIH®)
Countries where registered and available	Not available
Instructions for use languages available	Not available
Pricing (US$ per test)	Based on annual volume and if long-term agreements apply
Sale mechanism (directly to consumers/ intermediary marketing/both)	The product is designed for public health use and will be sold directly to non-governmental organizations and funders or in-country through local distributors.
Minimum order size for intermediary marketing	To be determined
Additional details	Not available

Annex 9.
Product specifications for HIV self-test kits with national-level approval in selected countries

The following product specification sheets include information provided by manufacturers of HIV self-test kits with national-level approval in selected countries. The information from manufacturers, including the sensitivity and specificity reflects what is stated in manufacturer instructions for use and what is recognized by the relevant regulatory authority. HIV self-test generation was reviewed by WHO prequalification against their records, where available. The manufacturers reviewed information related to their products prior to publication.

Please note detailed information for some of the eligible products in this category could not be obtained.

Action!

Product specification	
Manufacturer	Orangelife Comércio e Indústria LTDA
Manufacturing site	Brazil
Professional test basis (commercial professional use name – trademark)	N/A
Approvals for professional use product	Not available
HIV-self test product information	
Commercial name (trademark)	Action!
Product photo	
Type of technology	Immunochromatography
Test generation	Not available
Antigen type	p24, gp41, gp36
Output	Qualitative immunoassay, HIV-1/2 antibody detection
Controls	The test has an internal control line to indicate that specimen has well migrated.
Sensitivity	99.9%*
Specificity	99.9%*
Invalid rate	Not available

*Sensitivity and specificity based on assessment from ANVISA.

Action! (continued)	
Sample type	Whole blood
Capacity	Single specimen – one-time use
Volume of sample required	10 µL
Volume of buffer required	3 drops of buffer (~100 µL)
Time to result	Do not read before 10 minutes
Read window	Do not read after 20 minutes
Protocol complexity – steps required	1. Remove cap from safety lancet and apply to finger. 2. Collect sample using capillary tube; fill until the blood reaches the blue mark (10 µL). 3. Place sample into test device. 4. Add 3 drops of buffer solution to the sample. 5. Interpret test result.
Shelf life of test kit	24 months
Storage requirements	Store at room temperature up to 30 C°. The test is sensitive to humidity. Do not store in direct sunlight.
Test kit components	Test device, buffer, lancet, capillary tube, bandage, alcohol sachet, instructions for use and leaflet.
Not included in test kit	Timer
Restrictions for use	Do not open pouch until ready to perform test. Do not use beyond expiration date.
Approval status	Approved by Anvisa/Brazil (National Sanitary Surveillance Agency). Plan to pursue CE Mark approval.
Countries where registered and available	Brazil
Instructions for use languages available	Not available
Pricing (US$ per test)	US$ 9.8 (free-on-board*)
Sale mechanism (directly to consumers/ intermediary marketing/both)	Both
Minimum order size for intermediary marketing	1000 units
Additional details	Test kit has not been evaluated formally among people using ART drugs for prevention (for example, PrEP or PEP). Anticoagulants such as heparin, EDTA and citrate do not affect the result. Relevant interferons known as haemolytic samples, rheumatoid factor, icteric, haemolysed and lipemic samples may impair test results. http://testeaction.com.br/

*Free on board: This includes ex-works price plus freight cost to distributors.

Amethyst HIV 1&2 Test Kit

Product specification	
Manufacturer	Bedford Biotech Nigeria
Manufacturing site	China
Professional test basis (commercial professional-use name – trademark)	AMETHYST® HIV 1&2 Test Kit
Approval status for professional-use product	National Institute for the Control of Pharmaceutical and Biological Products (NICPBP), China Federal Ministry of Health, Nigeria The manufacturer plans to pursue WHO prequalification
HIV-self test product information	
Commercial name (trademark)	AMETHYST® HIV 1&2 Test Kit
Product photo	
Type of technology	Colloidal gold – Immunochromatography (lateral flow)
Test generation	3rd
Antigen type	Double antigen sandwich principle gp36, gp41, gp120
Output	Qualitative immunoassay, HIV-1/2 combined antibody detection
Controls	Built-in procedural control (a colour band at control region appears, indicating device is functioning properly).
Sensitivity	93.9%*
Specificity	92.8%*
Invalid rate	0.1%
Sample type	Oral fluid
Capacity	Single specimen – one-time use
Volume of sample required	0.3–0.5 mL (collected with oral swab) 3–4 drops into the test cassette.
Volume of buffer required	1 mL
Time to result	Do not read before 10 minutes
Read window	Do not read after 30 minutes

*Sensitivity and specificity based on report from NAFDAC.

Amethyst HIV 1&2 Test Kit (continued)	
Protocol complexity – steps required	1. Collect sample (oral swab). 2. Remove test tube cap. 3. Insert sample swab into test tube containing buffer solution and push up and down 6-8 times. 4. Remove sample swab from test tube. 5. Draw sample from test tube with pipette and add 3-4 drops into test cassette. 6. Interpret test result.
Shelf life of test kit	18 months
Storage requirements	4–30 ^{0}C. Store in dry environment, avoid direct sunlight.
Test kit components	Foil pouch containing test cassette and desiccant, buffer tube, pipette dropper, oral swab and instructions for use.
Not included in test kit	Timer
Restrictions for use	A test kit is for single use only. Wait 30 minutes after eating or drinking before test. Remove dentures before collecting sample. Do not use after expiration.
Approval status	Federal Ministry of Health, Nigeria
Countries where registered and available	Nigeria
Instructions for use languages available	English, other languages on request
Pricing (US$ per test)	US$ 14 recommended market price. Price for government and partner nongovernmental organizations may vary.
Sale mechanism (directly to consumers/ intermediary marketing/both)	Both
Minimum order size for intermediary marketing	No minimum order
Additional details	www.bedfordbiotech.com

Annex 10.
Product specifications for HIV self-test kits under development

The following product specification sheets include information provided by manufacturers of HIV self-test kits under development. The information included is solely based on information provided by manufacturers as the products are under development and not yet approved by any regulatory authority. The manufacturers reviewed information related to their products prior to publication.

Asanté™ HIV Self Test

Product specification	
Manufacturer	Sedia Biosciences Corporation
Manufacturing site	Portland, Oregon, United States of America
Professional test basis (commercial professional-use name – trademark)	Asanté™ HIV-1/2 Oral Fluid Rapid Test
Approvals for professional use product	Pursuing WHO prequalification
HIV-self test product information	
Commercial name (trademark)	Asanté™ HIV Self Test
Product photo	
Type of technology	Lateral flow immunoassay
Antigen type	Recombinant gp41, p24-gp41 fusion protein, recombinant gp36
Output	Qualitative immunoassay, HIV-1/2 antibody detection
Controls	In development
Sample type	Oral fluid. Combo version also using blood/ serum/plasma in development.
Capacity	Single specimen – one-time use
Volume of sample required	1 swab of oral mucosal transudate (~0.3 to 0.5 mL) OR 5 µL of blood, serum or plasma
Volume of buffer required	1.0 mL
Time to result	Do not read before 20 minutes
Read window	Do not read after 45 minutes

Asanté™ HIV Self Test (continued)	
Protocol complexity – steps required	1. Collect sample (oral swab OR finger stick). 2. Place sample into sample buffer tube and mix. 3. Remove swab or loop. 4. Drop test strip into sample buffer tube. 5. Interpret test result visually or using handheld reader.
Shelf life of test kit	Minimum 2 years
Storage requirements	Store at 2–30 ^{0}C
Test kit components	Pouched test strip with desiccant, sample buffer tube with sample buffer (1.0 mL), oral fluid collection swab, blood collection loop, instructions for use.
Not included in test kit	Lancets, alcohol wipes, handheld reader (reader sold separately), timer
Restrictions for use	The product has not yet been evaluated among people using ARV for prevention (PrEP or PEP). Not intended for use in screening blood, plasma, cell or tissue donors.
Instructions for use languages available	English
Additional details	http://www.sediabio.com/products/rapid-oral-hiv-1-2-test

Aware™ Oral HIV Self Test

Product specification	
Manufacturer	Calypte Biomedical Corporation
Manufacturing site	To be determined
Professional test basis (commercial professional-use name – trademark)	Aware™ HIV-1/2 OMT, Oral HIV Rapid Test
Approvals for professional-use product	Not available
HIV-self test product information	
Commercial name (trademark)	Aware™ Oral HIV Self Test
Product photo	
Type of technology	Immunochromatography (lateral flow)
Antigen type	gp36, gp41
Output	Single-use, qualitative, visually read in vitro immunoassay for detection of HIV-1/2 antibody in human oral mucosal transudate
Controls	The test has an internal control, in the form of a coloured band, indicating sufficient human specimen has been collected.
Sample type	Oral fluid
Capacity	Single specimen – one-time use
Volume of sample required	Not available
Volume of buffer required	180 to 500 µL
Time to result	Do not read before 20 minutes
Read window	Do not read after 45 minutes
Protocol complexity – steps required	1. Insert test tube containing buffer solution into stand. 2. Remove test tube cap. 3. Collect sample (oral swab). 4. Insert sample swab into test tube and push up and down 6-8 times. 5. Remove sample swab from test tube. 6. Insert test trip into test tube. 7. Interpret test result.

AwareTM Oral HIV Self Test (continued)	
Shelf life of test kit	18 months (unopened)
Storage requirements	Store between 2°–30 C°. Do not freeze.
Test kit components	Test kit box (used as test tube stand) containing: instructions for use, capped test tube (containing buffer), plastic pouch (containing 1 oral fluid collection swab), foil pouch (containing 1 test strip and 1 desiccant), instructions for use
Not included in test kit	Timer
Restrictions for use	This test is not intended for use by persons with HIV who are on ART. If you wear removable false teeth or dentures, take them out of your mouth before collecting the oral sample. Do not eat or drink for 10 minutes before starting test. Keep away from small children. Use within 7 days of opening.
Instructions for use languages available	English Afrikaans, EU and Kiswahili under development.
Additional details	Not available

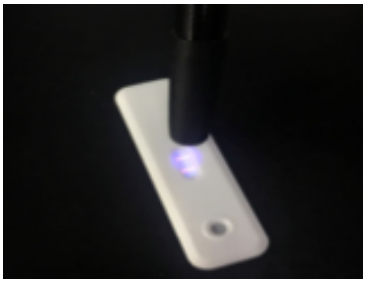
First Response HIV 1-2.0 Card Test (Self Test)

Product specification	
Manufacturer	Premier Medical Corporation Private Limited
Manufacturing site	Valsad, Gujarat, India
Professional test basis (commercial professional-use name – trademark)	First Response HIV 1-2.0 Card Test
Approvals for professional-use product	WHO prequalification
HIV-self test product information	
Commercial name (trademark)	First Response HIV 1-2.0 Card Test (Self Test)
Product photo	
Type of technology	Immunochromatography (lateral flow)
Antigen type	gp41, gp36
Output	Qualitative detection of antibodies specific for HIV-1 and HIV-2
Controls	Not available
Sample type	Whole blood
Capacity	Single specimen – one-time use only.
Volume of sample required	1 drop
Volume of buffer required	2 drops
Time to result	Do not read until 15 minutes
Read window	Do not read the results after 20 minutes
Protocol complexity – steps required	To be determined
Shelf life of test kit	24 months
Storage requirements	4–30 C°
Test kit components	Individually pouched test device with desiccant and specimen transfer device, alcohol swab, dry swab, sterile lancet, assay buffer vial, bandage and instructions for use.
Not included in test kit	Timer
Restrictions for use	Not available
Instructions for use languages available	English
Additional details	Not available

To be named (Abbott Laboratories)

Product specification	
Manufacturer	Abbott Laboratories
Manufacturing site	Hangzhou, China
Professional test basis (commercial professional-use name – trademark)	ABON™ HIV 1/2 Human Immunodeficiency Virus Rapid Test Device
Approvals for professional-use product	Not available
HIV-self test product information	
Commercial name (trademark)	To be determined
Product photo	Not available
Type of technology	Immunochromatography (lateral flow)
Antigen type	Recombinant antigen (including HIV-1 gp41 and HIV-2 gp36)
Output	Qualitative immunoassay for the detection of antibodies to HIV-1/2
Controls	Internal procedural controls are included in the test.
Sample type	Whole blood/serum/plasma
Capacity	Single specimen – one-time use
Volume of sample required	25 µL
Volume of buffer required	1 drop (40 µL)
Time to result	Do not read before 15 minutes
Read window	Do not read after 20 minutes
Protocol complexity – steps required	To be determined
Shelf life of test kit	24 months
Storage requirements	2–30 C°
Test kit components	To be determined
Not included in test kit	Timer
Restrictions for use	Do not use after expiration date. Do not eat, drink or smoke in the area where the specimens or kits are handled. Humidity and temperature can adversely affect results.
Instructions for use languages available	English
Additional details	Not available

To be named (Beijing Wantai)

Product specification	
Manufacturer	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.
Manufacturing site	Changping District, Beijing, China
Professional test basis (commercial professional-use name – trademark)	Rapid Test for Antibody to HIV-1 in Urine (Fluorescent Immunochromatographic Assay)
Approval status for professional-use product	Registration in China pending
HIV-self test product information	
Commercial name (trademark)	To be determined
Product photo	
Type of technology	Fluorescent immunochromatographic assay
Antigen type	Recombinant HIV-1 antigen, gp160 and gp41
Output	Qualitative fluorescence
Controls	Integrated control line. No separate quality controls are available.
Sample type	Urine
Capacity	Single specimen – one-time use
Volume of sample required	7 ml
Volume of buffer required	None required, specimen is added directly to test cassette.
Time to result	15 minutes after sample is applied
Read window	Not yet established; goal is 30 minutes
Protocol complexity – steps required	1. Collect urine sample. 2. Add approximately 80 µL of urine to the test cassette. 3. Interpret test results with UV-pen.
Shelf life of test kit	Not established, expected – 12 months
Storage requirements	2–30 C°
Test kit components	Test cassette in foil pouch with desiccant, buffer, UV-pen or other UV emitting device, urine collection cup.

To be named (Beijing Wantai)	
Not included in test kit	Timer
Restrictions for use	Only for detection of HIV-1; not for HIV-2
Instructions for use languages available	Chinese and English (under way)
Additional details	Not available

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