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MARKET AND TECHNOLOGY LANDSCAPE

HIV RAPID DIAGNOSTIC TESTS FOR SELF-TESTING

3rd EDITION

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Abbreviations

ART	antiretroviral therapy
ARV	antiretrovirals
CDC	Centers for Disease Control and Prevention
CE	European Conformity
DNA	deoxyribonucleic acid
ERPD	Expert Review Panel for Diagnostics
FDA	United States Food and Drug Administration
GHTF	Global Harmonization Task Force
GMP	Good manufacturing practice
HIV	human immunodeficiency virus
HIVST	HIV self-testing
IFU	instructions for use
IPV	intimate partner violence
IVD	in vitro diagnostic
ISO	International Organization for Standardization
LMIC	low and middle-income countries
mL	mililitre
µL	microlitre
NA	not available
NAT	nucleic acid testing
NGO	nongovernmental organization
PEP	post-exposure prophylaxis
PEPFAR	President's Emergency Program for AIDS Relief
PLHIV	people living with HIV
PMA	pre-market approval
PQ	prequalification
PrEP	pre-exposure prophylaxis
PSI	Population Services International
RDT	rapid diagnostic test
RNA	ribonucleic acid
SMS	short message service
STI	sexually transmitted infection
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
USA	United States of America
USAID	United States Agency for International Development
US $	United States dollar
VMMC	voluntary medical male circumcision
WHO	World Health Organization

Executive Summary

This third edition of the *Unitaid/WHO market and technology landscape: HIV rapid diagnostic tests for self-testing* report summarizes the current HIV testing gap; the challenges facing efforts to scale up; and the potential role HIV self-testing (HIVST) could play to achieve the United Nation's 90-90-90 targets. In particular, the report synthesises the existing and emerging market demand and supply of kits. The information in this report is intended for manufacturers, donors, national programmes, researchers and other global health stakeholders who are exploring the potential role of HIVST.

An individual's knowledge of their and their partner's HIV status is essential to the HIV response. Despite the many benefits of HIV testing, in 2016, approximately 30 per cent of people with HIV remained unaware of their status. Some of the largest gaps in testing, prevention and treatment coverage are among men, young people and key populations who are often reluctant or unable to access existing services. Recognizing this, the World Health Organization (WHO) recommended that HIVST be offered as an approach to complement existing HIV testing approaches. Since then, HIVST has been scaling up rapidly.

As of July 2017, there is one WHO prequalified HIV self-test. In addition, there are an increasing number of HIVST products on the market (using oral fluid and whole-blood specimens) that are registered and approved by a founding member of the Global Harmonization Task Force (GHTF), have been submitted to WHO prequalification, or have been recommended for donor procurement by the Unitaid/Global Fund Expert Review Panel four Diagnostics (ERPD) upon programmes' requests. In addition, four countries: Brazil, China, Kenya and Nigeria, each have one HIVST product manufactured and registered for use in-country.

Retail prices of available products in high-income countries range from US$ 22–48 per test in the private sector and from US$ 7.50–15.00 per test in the public sector. In low and middle-income countries

(LMICs), public-sector pricing for HIVSTs has ranged from US$ 3-6 per test in the public sector to US$ 8-16 in the private sector.

The HIVST market is still nascent and many products are under development. To date, all HIVST products are serology assays, the majority of which are second-generation rapid diagnostic tests (RDTs) that require five to seven steps and include a time to result of between 1 and 45 minutes. Despite the growing market and introduction of new products, significant innovations and modifications of RDTs are needed to improve ease-of-use and interpretation, instructions for use, packaging, robustness and durability.

HIV policies and pathways are becoming increasingly clear. As of July 2017, 40 countries had adopted policies enabling HIVST implementation, with 13 reporting ongoing implementation, and another 48 with policies under development. Such increases have begun to stimulate demand. Between 2012 and 2017, approximately 2.5 million HIVST kits were sold worldwide. While HIVST use is growing in high-income markets, HIVST use in LMICs is only now beginning to appear outside of research and pilot programmes. However, with an HIVST product now prequalified by WHO, implementation is only expected to increase.

Planned investments to scale HIVST, such as within the Unitaid-funded Self-Test Africa (STAR) initiative, will provide increased clarity around demand, public-sector distribution and consumer preferences. Investments made by the Children's Investment Fund Foundation (CIFF) and the Bill & Melinda Gates Foundation will facilitate demand and provide greater clarity on the potential of some markets. For example, the Bill & Melinda Gates Foundation recently announced an agreement to lower the price per test of an HIVST (namely, the OraQuick® HIV Self Test) to US$ 2.00 across 50 high HIV burden and/or LMICs.

Based on country commitments to date, at least 4 million HIVST kits are expected to be procured by donor-funded programmes from July 2017 to the end of 2018. The majority of these kits are expected to be procured under the STAR initiative, followed by the Global Fund and PEPFAR programmes. The number of HIVST kits to be procured is expected to grow, as more than 20 LMICs report that they are planning to implement HIVST using resources from PEPFAR and/or the Global Fund starting in 2018, and grant-making is still underway. However, the scale of government and donor support for developing an HIVST market remains uncertain. Investment decisions will likely be driven by the overall cost of HIVST - including product and delivery costs - as well as its overall cost-effectiveness, and its public health impact measured through reductions in HIV incidence and HIV-related mortality and morbidity.

There are a number of positive signs with respect to the introduction, implementation and scale-up of HIVST. Introduction of the WHO guidelines on HIVST and WHO prequalification of the first HIVST product for self-testing in 2017, have particularly helped create greater certainty in terms of regulatory and policy pathways. The guidelines have also resulted in a surge in the number of countries with policies supportive of HIVST, and have helped facilitate increases in planned procurement. However, major risks remain. These include limited product innovation, variable and non-transparent regulatory pathways and guidelines at the country level, and uncertain demand. To maximize the potential and to continue to expand the HIVST market, governments, donors and manufacturers must continue to work together to address these risks.

Background

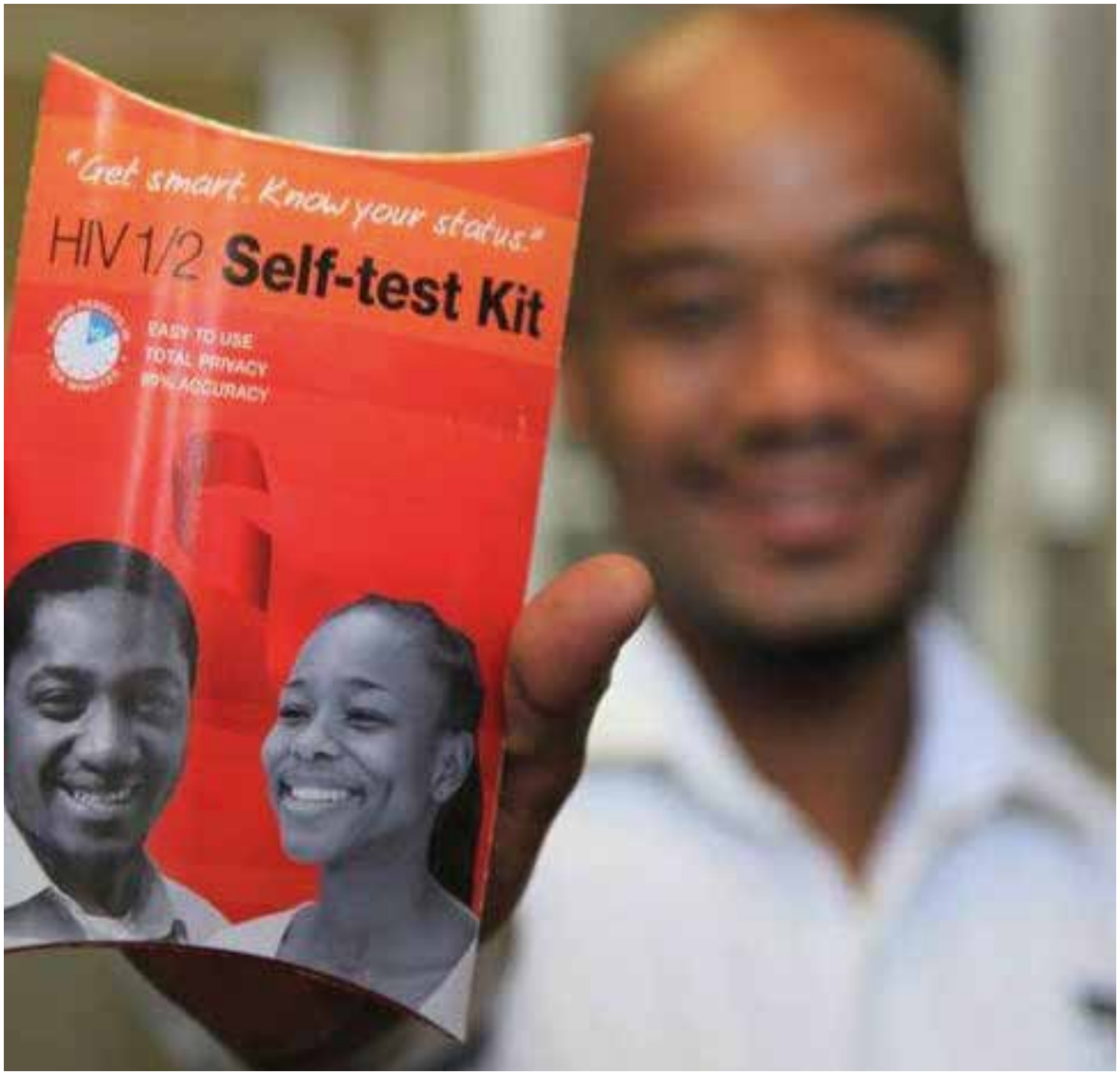
Public health problem

A person's knowledge of their and their partner's HIV status is essential to the success of the HIV response. HIV testing services are the gateway to treatment, prevention and care. Implementation of HIV prevention and treatment services, including the offer of antiretroviral therapy (ART) to all people living with HIV (PLHIV), is highly effective in reducing HIV-associated morbidity and mortality and can prevent onward transmission of HIV [1-3]. The United Nations (UN) fast-track targets have been set to enable the end of the HIV/AIDS epidemic, starting with diagnosing 90 per cent of all PLHIV by 2020 [4].

To date, the global scale-up of HIV testing services has been significant. Between 2010 and 2014, more than 600 million people received HIV testing services in 122 low- and middle-income countries (LMICs) [5]. In 2015, it was estimated that 55 per cent of PLHIV in Africa were aware of their HIV status [6, 7], an increase from 2005 when only 10 per cent of PLHIV in Africa were aware of their status [8]. These gains have been made possible through the expanded use of rapid diagnostic tests (RDTs), implementation of routine testing in health facilities (primarily in antenatal care and tuberculosis clinics), and expansion of community-based HIV testing and task-sharing initiatives enabling trained lay providers to perform HIV testing services. With the widespread availability of ART and the widespread use of RDTs, which in a validated testing algorithm can often provide a same-day diagnosis, HIV testing is now routinely provided to patients with brief pre-test information and post-test counselling—without the requirement for pre-test counselling [9].

Despite achievements in scaling-up HIV testing, substantial gaps remain. Globally, approximately 30 per cent of all PLHIV do not know their status [10]. In many settings, where a growing number of HIV tests are performed every year, many of these tests do not necessarily reach PLHIV who are unaware of their status or others who are at high risk of HIV infection [9]. For instance, although 150 million HIV tests were performed in 2014 in 122 LMICs, in this same period, 81 of these countries reported that only 3 per cent of all HIV tests performed were positive [5].

Men continue to have lower testing rates than women in nearly all countries [5]. Nearly 70 per cent of adult HIV tests reported in 76 LMICs in 2014 were among women [5]. Demographic Health Surveys (DHS) between 2013 and 2016 also show many men, compared to women, still report never having an HIV test [11]. Global reporting suggests this is because HIV testing has been successfully integrated within reproductive health services, including antenatal care, but not consistently in other clinical settings, and male-partner testing and partner notification services are not widely implemented [9, 12, 13]. Thus, many men remain untested and those with HIV often continue to be diagnosed late [14].



Source: Krista Dong, iTEACH

Key populations[1] continue to comprise nearly half of new HIV infections each year [11]. Testing coverage remains low among these populations, and existing reports of coverage are likely overestimates due to limited data that are not representative [15]. Low uptake of HIV testing services among key populations is not only related to availability, but also the lack of acceptability due to unfriendly services, fear of stigma, discrimination, and criminalisation of behaviour [15].

Young people and adolescents, particularly girls and young women in sub-Saharan Africa, are also at significant HIV risk. Approximately 7500 young women (15-24 years) acquired HIV every week in 2015; the majority of whom were in southern Africa [6]. Yet, adolescents remain less tested than adults. Findings from DHSs in 19 LMICs, between 2011 and 2015, report half of 15-19 year olds testing HIV-positive were first-time testers and previously unaware of their HIV status [6]. Uptake of testing is constrained by a lack of quality testing services, and further exacerbated by restrictive laws and policies such as age of consent laws that prevent adolescents from accessing HIV testing [16].

In order to close these gaps and achieve the UN 90-90-90 targets, scale-up of efficient and effective HIV testing approaches are essential. A key challenge to this scale-up, however, is the shortage of health workers. In 2013, it was estimated that there was a net shortage of 6.5 million health workers [17]. Since then, this gap has grown. Recent estimates suggest by 2030 there will be a net shortage of 15 million health workers, with shortages having the greatest impact in LMICs [17].

These challenges require a new focus and new approaches to reach PLHIV who remain undiagnosed early in their infection. Many countries and programmes are considering innovative approaches to delivering HIV testing services to adequately reach these people and achieve national and global testing targets.

[1] The WHO defines key populations as groups who, due to specific higher-risk behaviours, are at an increased risk of HIV irrespective of the epidemic type or local context, including people in prison, people who inject drugs, men who have sex with men, sex workers and transgender people.

Source: Unitaid/Eric Gauss

HIV testing technologies for the point-of-care

Currently, there are two key categories of HIV testing technologies that can be used at the point-of-care: HIV RDTs and nucleic acid testing (NAT) technologies.

HIV RDTs are serology assays that detect HIV-1/2 antibodies and/or HIV-1 p24 antigen. HIV RDTs generally provide results within 1 and 20 minutes and are in the form of lateral flow, e.g. strips or cassettes, or immunofiltration devices, e.g. flow-through devices. When used within a national validated testing algorithm, they can accurately provide a same-day diagnosis. They are relatively easy to use, can be performed using capillary whole blood or oral fluid specimens, contain built-in quality controls and can be administered by trained non-laboratory personnel (e.g. health workers and lay providers).

A nucleic acid test (NAT) is a molecular technology for detecting the presence of HIV in RNA and/or DNA in plasma, venous and capillary whole blood or dried blood spot specimens. Few NAT technologies can be used at the point of care. Those that are available for use at the point of care are used primarily for early-infant diagnosis in LMICs and generally not used or validated for adult diagnosis. Therefore, this landscape will not discuss NAT technologies.

Depending on which assays are used, HIV infection can generally be detected by a serology assay between 14 and 50 days following the initial infection. HIV RDTs currently in use can be classified into three groups (second-, third- and fourth-generation tests) based on how soon after exposure they can potentially detect an HIV infection.

- Second generation HIV RDTs only detect HIV-1/2 antibodies and can typically detect HIV beginning 28 days after an exposure.
- Third generation HIV RDTs only detect HIV-1/2 antibodies and can typically detect HIV beginning 21 days after an exposure.
- Fourth generation HIV RDTs detect both HIV-1/2 antibodies and p24 antigen. These RDTs can identify an infection beginning 14 days after an exposure. While theoretically they may be able to detect early/acute HIV infection, field evaluations suggest that this has not been demonstrated in practice [18, 19].

The HIVST imperative: Global evidence

HIVST has been proposed as an additional approach to help countries achieve the first 90 of the UN targets for HIV [20]. In 2016, WHO recommended HIVST be offered as an additional HIV testing approach [20] (see Box 1). WHO defines HIVST as a specific process in which a person collects his or her specimen (e.g. oral fluid or fingerstick blood) and then performs a test and interprets the result, often in private or with someone they trust. All individuals with a reactive self-test result must receive further testing from a trained provider using a complete, validated testing algorithm for diagnosis [20].

Box 1. KEY EVIDENCE ON HIV SELF-TESTING (HIVST) IN 2016 WHO GUIDELINES

HIVST:

- *Is highly acceptable among various groups of users and in different settings.*
- *Doubles the uptake of HIV testing among men who have sex with men and male partners of pregnant or postpartum women compared to facility-based testing.*
- *Increases uptake of couples HIV testing among male partners of pregnant or postpartum women compared to facility-based testing.*
- *Nearly doubles frequency of HIV testing among men who have sex with men compared to facility-based testing.*
- *Can be accurate and an HIV RDT used by a self-tester can perform just as well as an HIV RDT used by a trained tester.*
- *Can result in identifying an equivalent or greater proportion of HIV-positive people compared to standard testing.*
- *Does not increase HIV risk behaviour and does not decrease uptake or frequency of testing for sexually transmitted infections (STIs) compared to standard testing.*
- *Is safe and does not increase social harm or adverse events compared to standard testing.*
- *Can be cost-effective and has potential to increase efficiency of HIV testing and reduce client's cost of seeking services.*

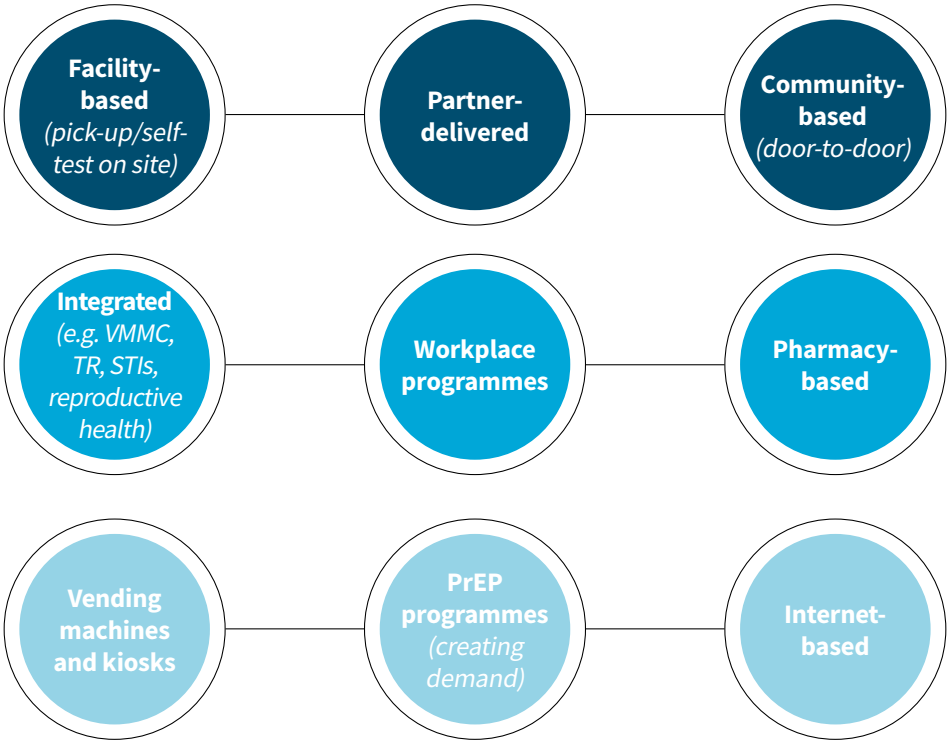
Source: WHO 2016 [20].

The potential benefits of HIVST have been particularly highlighted for people in need of testing who are unable or hesitant to access existing services, as well as those in need of more frequent retesting because of high ongoing risk [9, 20, 21]. In addition to increasing uptake and frequency of testing, HIVST may also lead to early diagnosis and linkage to prevention and treatment, as well as possible health systems efficiencies. By directing those with a reactive self-test to confirmatory testing and those with a nonreactive test to relevant HIV prevention methods or other health services, HIVST may reduce the time required to deliver full HIV testing services, saving both clients and health workers time [20].

There are many approaches to implementing HIVST that can be adapted given the context, the population, and the geographic setting (Figure 1). These approaches vary by type (direct or indirect assistance) and level of support provided, as well as how and where HIVST kits are distributed [20].

Although limited, evidence suggests linkage to further testing and onward HIV prevention and treatment services can be good for patients. Studies have shown HIVST plus home-based assessment or care can be particularly effective [22], as well as community-based approaches to distribution [23], and couples and partner self-testing [24]. According to the latest results from the STAR project[1], using primarily community-based distribution, 80 per cent of male self-testers with a reactive result in Zimbabwe have linked to ART. Box 2 highlights tools that may also enhance linkage to further testing, prevention, treatment and care following HIVST.

FIGURE 1.
HIVST service-delivery approaches



Source: WHO, 2016 [20].

[1] Personal communication STAR Project, 29 June 2017.

Box 2. INTERVENTIONS AND TOOLS TO SUPPORT LINKAGE FOLLOWING HIVST

- ***Home-based treatment initiation with support and active follow-up by community-based networks*** *has been shown to be an effective way to support linkage to care [22].*
- ***Package inserts*** *explaining the importance of further testing, and where and how to obtain prevention, treatment, and care services.*
- ***Telephone hotlines*** *that provide information, including psychosocial, technical support, and referral information for prevention, treatment and care and other non-medical services (i.e. legal support; redress for violence).*

Source: LVCT Kenya

- ***Mobile phone services****, which can operate like hotlines, can use short message service (SMS), videos and phone call to encourage linkage.*
- ***Internet- and computer-based programmes*** *can provide online two-way audio or video counselling services that give step-by-step instruction on what to do following a reactive self-test result, including descriptions of where and how to obtain further testing, prevention, treatment and care.*
- ***Vouchers, coupons, financial incentives or rebates*** *could play an important role for populations that face structural barriers to accessing services, such as long distances and costly transportation.*
- ***Referral or appointment cards*** *that provide a contact, date and/or time for an appointment for follow-up services, including HIV testing and other HIV prevention, treatment and care services could also be used to facilitate linkage.*
- ***Partner HIVST*** *may increase linkage to care and encourage male involvement [24]. Offering HIVST within partner notification services also may promote linkage to prevention, treatment and care.*

Global HIVST supply

Current HIVST technology builds on the existing supply of professional-use HIV RDTs, summarized in Box 3. In fact, nearly all HIVST products being developed are adapted and repackaged versions of these professional tests. However, many modifications, including improved packaging and instructions for use, need to be made to existing professional-use HIV RDTs to optimize the products for HIVST.

Box 3. SUMMARY OF PRICING, SUPPLY AND MARKET OF PROFESSIONAL-USE HIV RDTS

While the market for HIVST is still emerging, with only one HIVST product prequalified by WHO, the overall market of professional-use HIV RDTs is relatively large and well established. In 2015, 52 unique professional use HIV RDTs were identified, the majority of which (48) used fingerstick/whole blood [25]. As of June 2017, according to listings by the WHO[1] or the Global Fund[2], 24 HIV RDTs for professional use are eligible for procurement by primary donors. Of those listed, 15 fingerstick/whole blood-based RDTs and two oral fluid-based RDTs are WHO prequalified. Nearly all are second- or third-generation assays, with only two fourth-generation assays listed. See Annex 1 for summary of products listed by WHO or the Global Fund.

In 2016, approximately 102 million HIV RDTs for professional use were reportedly procured by the Global Fund, PEPFAR, UNICEF, and WHO[3]. Pricing of HIV RDTs for professional use was varied, with ex-works price[3] ranging from approximately US$ 0.55 to US$ 3.42 per test. Overall, 90 per cent of the volumes of HIV RDTs were procured at prices below US$ 1.05; the majority of which were one product.

Source: WHO, Personal communication, Mercedes Pérez Gonzalez, 17 July 2017; PSI, Personal communication, Patrick Aylward, 17 July 2017

[1] WHO Prequalification of IVDs Programme list of prequalified products 3 May 2017: http://www.who.int/diagnostics_laboratory/evaluations/170503_prequalified_product_list.pdf
[2] Global Fund listing 31 March 2017: https://www.theglobalfund.org/media/5878/psm_productshiv-who_list_en.pdf
[3] Ex-works prices are determined at the manufacturer's factory, and do not include any delivery, distribution, taxes or commission charges.

HIVST kit target product profile

Although HIV RDTs are widely available and generally effective in the hands of a professional user, they may not always be best suited for self-testing. In 2014, PATH developed a baseline target product profile for HIVST [26], which set out characteristics for HIVST that would be reviewed and updated. The summary below provides an overview of that initial profile, as well as some additional considerations for the ideal HIV RDT for self-testing.

Test generation.
At the moment, the HIVST products on, and emerging in, the market are primarily second-generation HIV RDTs. The use of second-generation HIV RDTs for self-testing has raised some concerns; however, they fit the needs of the current market.

Although there are some discussions about the possibility of an HIVST kit that can be used in the context of PrEP, this is expected in the future and would require further feasibility studies. Nevertheless, adapting existing HIV testing technologies that have high seroconversion sensitivity, may be advantageous for populations that require frequent retesting and are at high risk for HIV (e.g. high incidence).

Source: Wang

Easy to use.

HIVST kits should be easy to use. Sample preparation should be simple and only a small number of operator steps, especially timed steps, should be required to perform the test. Each step for HIV testing, from the specimen collection to interpreting the final result, is critical for ensuring a correct result. The more steps, the greater the risk is for user error, which may in turn increase the risk of an incorrect test result. Collecting and transferring specimen (fingerstick/whole blood, oral fluid, potentially urine) has been shown to be particularly prone to error for self-testers, resulting in test system failures, invalid results and suboptimal performance [27]. Thus, an HIV RDT for self-testing with few steps, or ideally one single step, could substantially reduce the risk of a number of user errors. Opportunities to develop integrated components, such as specimen collection and transfer devices as well as integrated buffer systems may be useful, including painless lancets and easy-to-use components that regulate the volume of specimen collected and how the specimen is transferred.

Easy interpretation.

Interpretation of test results can be challenging, particularly if there are multiple lines, if lines are faint or blurred, if the size of the read-window is small, if the incubation time (time to result) is long, and if the read time (duration of valid test result) is short. Similarly, it can also be difficult for users if test results are not valid for an extended time after the test result appears. It is well-documented that errors interpreting RDT results occur even among trained users, for example, incorrect interpretation of “faint lines” and failure to read results within the stipulated time (either too early or too late) [27]. It is likely that using existing RDTs for self-testing will have similar challenges.

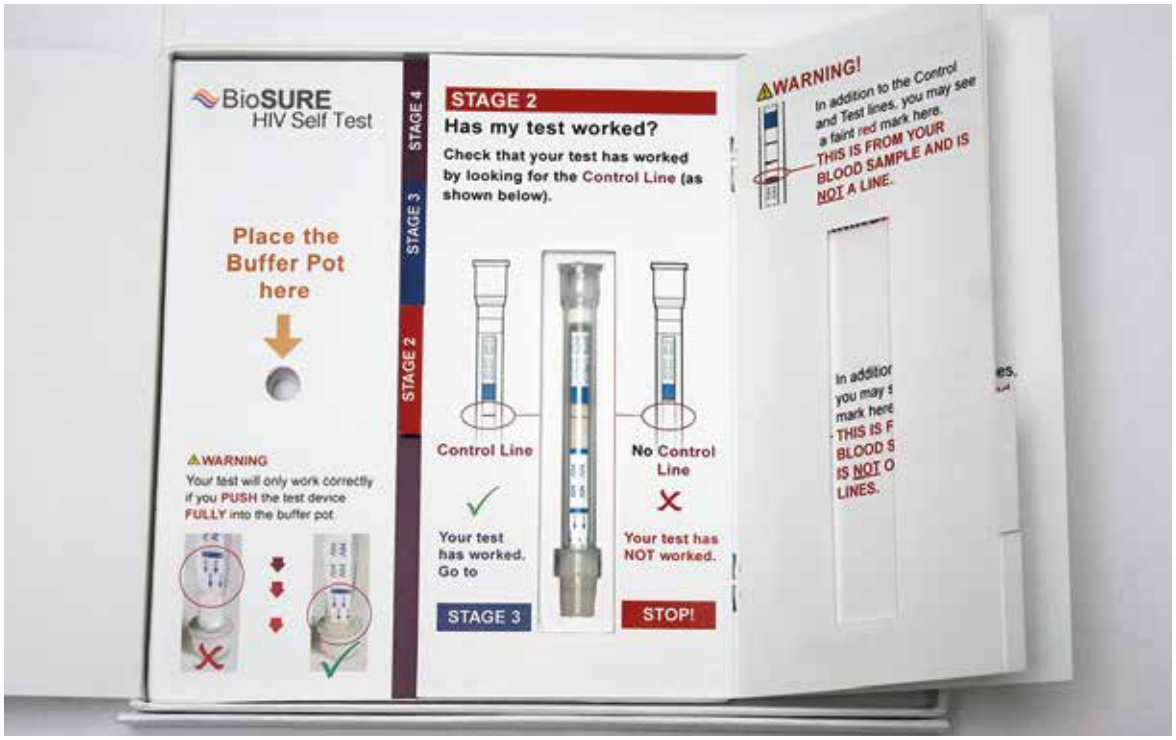
To address these challenges, an ideal RDT for self-testing should provide a result in one to five minutes and have a read window where results are stable for more than 60 minutes, after which they give an invalid result. Result windows should be clear and easy to read to facilitate correct interpretation of results. However, current HIV RDTs being used for self-testing do not have all of these characteristics. For example, while one HIV RDT for self-testing produces results and can be accurately read one minute after the sample is applied, the majority can be read in 15-20 minutes. And, the read windows for the majority of HIVSTs are less than 60 minutes.

Robustness and durability.

The ideal product design for HIV RDTs for self-testing should be robust, durable and able to sustain high temperatures and humidity, as well as survive extreme fluctuations in temperature; no cold chain should be required. Lastly, while robustness and durability are critical, packaging is also a key consideration to maximize product acceptability. Potential users may find bulky or heavy packaging unattractive, particularly those seeking privacy and discretion.

Instructions for use (IFU) and support tools.

Some studies indicate that HIV RDTs for self-testing perform best when IFUs have been developed and validated among intended user populations, including demonstrations [28]. Pictorial IFUs are necessary as literacy levels vary highly across intended user populations and settings. Because of cultural and language differences, special attention to detail will be needed as instructions will have to be translated and validated prior to implementation. However, providing additional support tools may also improve performance, such as demonstrations, brochures, hotlines and videos.



Source: Brigette Bard

Available and pipeline products

Currently, there is one WHO prequalified HIVST product available for procurement. This product, as well as several others which have been found eligible for procurement by the ERPD, can be procured with major donor funds including the Global Fund and Unitaid. (See Box 4).

Box 4. UPDATES ON THE EXPERT REVIEW PANEL FOR DIAGNOSTICS FOR PRODUCTS FOR HIVST

The Expert Review Panel for Diagnostics (ERPD), supported by Unitaid and the Global Fund and hosted by WHO, assesses the eligibility of needed in vitro diagnostics (IVDs) not yet prequalified by WHO and provides recommendations on their use, leading to temporary procurement eligibility by main donors. Such products will be procured upon request by countries and under specific processes determined by the Global Fund and Unitaid, respectively.

Two rounds of WHO ERPD evaluation of HIVST kits have already taken place in 2016 and 2017. In June 2017, Unitaid and Global Fund concluded the second round of evaluation of RDTs for HIVST in anticipation of a full review of these HIVST products for prequalification by WHO. In addition to the oral-fluid test previously recommended for procurement based on ERPD review (OraQuick® HIV Self-Test), several blood-based HIVST kits were identified that may be considered for procurement.

At the time of releasing this report, WHO prequalified the OraQuick® HIV Self-Test in July 2017. It is hoped additional products will now also undergo review and obtain approval.

Other products have also emerged that have undergone local, in-country approval processes. For example, the Action! HIVST product has been approved by the National Health Surveillance Agency (ANVISA) for use in Brazil [29], and the Amethyst HIV 1&2 Test Kit has been approved for use in Nigeria [30]. Several other self-test kits are submitting for approval for sale in China and other markets [31], such as the Rapid Test for HIV-1 Antibodies in Urine (fluorescent immunochromatographic assay) from Beijing Wantai.

The HIVST pipeline is large, with 10 fingerstick/whole blood-based, two oral fluid-based, one fingerstick/whole-blood or oral-fluid based, and one urine-based RDT for self-testing under development; some of which are already available in select markets (see Table 2). All products are serology tests. Nearly all use immunochromatography (lateral flow); one uses qualitative fluorescence and one uses immunofiltration (flow through).

Tables 1, 2 and 3 summarize the available products and current pipeline. Detailed product specifications can be found in Annex 2 and Annex 3.

TABLE 1.

Available HIV RDTs for self-testing prequalified by WHO and/or with approval from regulatory authorities in founding-member countries of the Global Harmonization Task Force

Brand name (Manufacturer/ Supplier)	Generation	Sensitivity	Specificity	Approval status	Markets	Price in US$ per test
autotest VIH® (AAZ Labs, France)	2nd	100.00%	99.80%	CE marked	Several in Europe[1]	HIC retail: 22-28 Distributor: 8 - 15 (volume dependent)
BioSURE HIV Self-Test (hardcase & softcase)+ (BioSURE, United Kingdom)[2]	2nd	99.70%	99.90%	CE marked	United Kingdom	HIC retail: 42 – 48 HIC public sector: 7.50 – 15 LMIC ex-works: 5
INSTI® HIV Self Test (box) (bioLytical Lab., Canada)	3rd	100.00%	99.80%	CE marked	Several in Europe[3]	HIC retail: 33
OraQuick® In-Home HIV Test* (OraSure Technologies., USA)	2nd	91.70%	99.98%	FDA	USA	HIC retail: 40
OraQuick® HIV Self Test* (OraSure Technologies, USA[4])	2nd	99.02%+	100%+	WHO PQ	Kenya, planning on South Africa	LMIC retail: 9.50 LMIC ex-works: 2 for 50 countries (see Box 5)

HIC: High income country
LMIC: Low and middle-income country
* The OraQuick® HIV Self Test has obtained WHO prequalification. 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
+ The listed performance criteria listed is based on the ERPD 2016 report.

[1] France, Belgium, Czech Republic, Netherlands, Poland, Portugal, and Spain. The company noted that the product may be available in additional countries, but did not specify.
[2] BioSure distributes two CE-marked products in the UK, one for private-sector distribution and the other for public-sector distribution. Though similar, the products have different packaging and are therefore considered different products but their reported performance is the same. Another version of the test, manufactured also in the UK and South Africa, is offered to LMICs at US$ 11.75 retail and US$ 5–6 ex-works
[3] France, United Kingdom, Belgium, Netherlands, Austria, Czech Republic, Ireland, and Italy
[4] The OraQuick® HIV Self-Test version for the rest of the world is manufactured in the USA but assembled in Thailand.

TABLE 2.

HIV RDTs for self-testing available in select private-sector markets

Assay name (Manufacturer /Supplier)	Specimen	Generation	Approval status	Availability	Pricing (US$)
Action! (Orangelife Comércio e Indústria LTDA, Brazil)	Whole blood	3rd	ANVISA; Brazil; Plans to apply for CE-mark.	Brazil	Free on board*: 14
Amethyst HIV 1&2 Test Kit (MYSP Nigeria Ltd., Nigeria)	Oral fluid	NA	Approved in Nigeria	Nigeria	Retail: 16
Atomo HIV Self Test (Atomo Diagnostics, Australia)	Whole blood	3rd	Approved in Kenya and sold in South Africa as i-test by Atomo's partner, Iyeza Health	Kenya, South Africa	Private sector retail: 13.40 Ex-works: 3 (volume dependent)
INSTI® HIV Self Test[1] (pouch) (bioLytical Laboratories, Canada)	Whole blood	3rd	Approved in Kenya; awaiting CE-mark	Kenya	Retail 8 – 10 Ex-works: 3

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

TABLE 3.

HIV RDTs for self-testing in the pipeline

Assay name (Manufacturer /Supplier)	Specimen	Generation	Availability	Pricing (US$)	Regulatory status
Alere Combo Self-Test for HIV (Alere Inc., USA)	Whole blood	4th	LMICs only	NA	Plans to apply to WHO PQ
Alere HIV Self-Test (Alere Inc., USA)	Whole blood	NA	Europe	NA	Pursuing CE-mark
Asanté™ HIV-1/2 Oral Fluid Rapid Test (Sedia Biosciences Corporation, USA)	Oral fluid or whole blood	2nd	NA	NA	Plans to apply for WHO PQ
Aware™ HIV-1/2 OMT Oral HIV Self Test (Calypte Biomedical, USA)	Oral fluid	2nd	NA	NA	Plans to apply for WHO PQ and CE- mark
Exacto® HIV Screening Test (Biosynex Medtech, France)	Whole blood	3nd	NA	NA	CE-mark pending

[1] The INSTI HIV Self-Test listed in this Table 2 is a modified form of its CE-marked product listed in Table 1. This product does not use a pipette for specimen transfer, employing a free-flowing blood drop, which the company refers to as a "pouch".

Assay name (Manufacturer /Supplier)	Specimen	Generation	Availability	Pricing (US$)	Regulatory status
Rapid Test for HIV-1 Antibodies in Urine (Fluorescent Immunochromatographic Assay) (Beijing Wantai Biological Pharmacy Enterprise Co., Ltd)	Urine	3rd	NA	NA	Submitting for approval in China
SURE CHECK® HIV Self Test (Chembio Diagnostic Systems, USA)	Whole blood	2nd	NA	NA	Plan to apply for WHO PQ and CE-mark
To be named (Premier Medical Corporation, India)	Whole blood	2nd	NA	NA	NA
To be named (Shanghai Kehua Bio-engineering Co., Ltd, Republic of Korea)	Whole blood	3rd	NA	NA	NA
To be named (Trinity Biotech, Ireland)	Whole blood	NA	NA	NA	NA

Product availability

High-income countries

There has been considerable expansion of the HIVST market in high-income countries since the first product was introduced in 2012. The OraQuick® In-Home HIV Test was approved by the United States Food and Drug Administration (FDA) in 2012, and several other products have been approved and become available in Western Europe, including autotest VIH®, BioSURE HIV Self-Test, and INSTI® HIV Self-Test.

In the USA and Western Europe, HIV RDTs for self-testing are generally sold in the private sector through pharmacy and internet channels. Private-sector prices range from US$ 22.00 to US$ 48.00 per test (see Table 1). In addition, BioSure sells a public-sector version of its product that utilizes different packaging to the National Health Service and nongovernmental organizations (NGOs) in the United Kingdom at a price of US$ 7.50 to 15.00 per test. While public-sector HIVST distribution has not played a large role in high-income markets, government subsidies and health insurance schemes to reimburse users who purchase HIVST kits are being developed and rolled-out.

Source: Terrence Higgins Trust

Low and middle-income countries

The Unitaid-funded STAR Program has been responsible for the vast majority of HIVST sales in sub-Saharan Africa, to date; however, additional public and private sector demand is beginning to emerge in a number of countries. Pricing for LMIC buyers in the public sector generally has ranged from US$ 3.00 to $6.00 (see Tables 1 and 2). However, in June 2017, the Bill & Melinda Gates Foundation announced an agreement with OraSure to decrease the price of its OraQuick® HIV Self-Test to US$ 2.00 (ex-works) for public-sector buyers in 50 countries (see Box 5).

Box 5. ORASURE TECHNOLOGIES ENTERS AGREEMENT WITH BILL & MELINDA GATES FOUNDATION TO REDUCE THE PRICE OF ORAQUICK® HIV SELF-TEST IN 50 LMICS

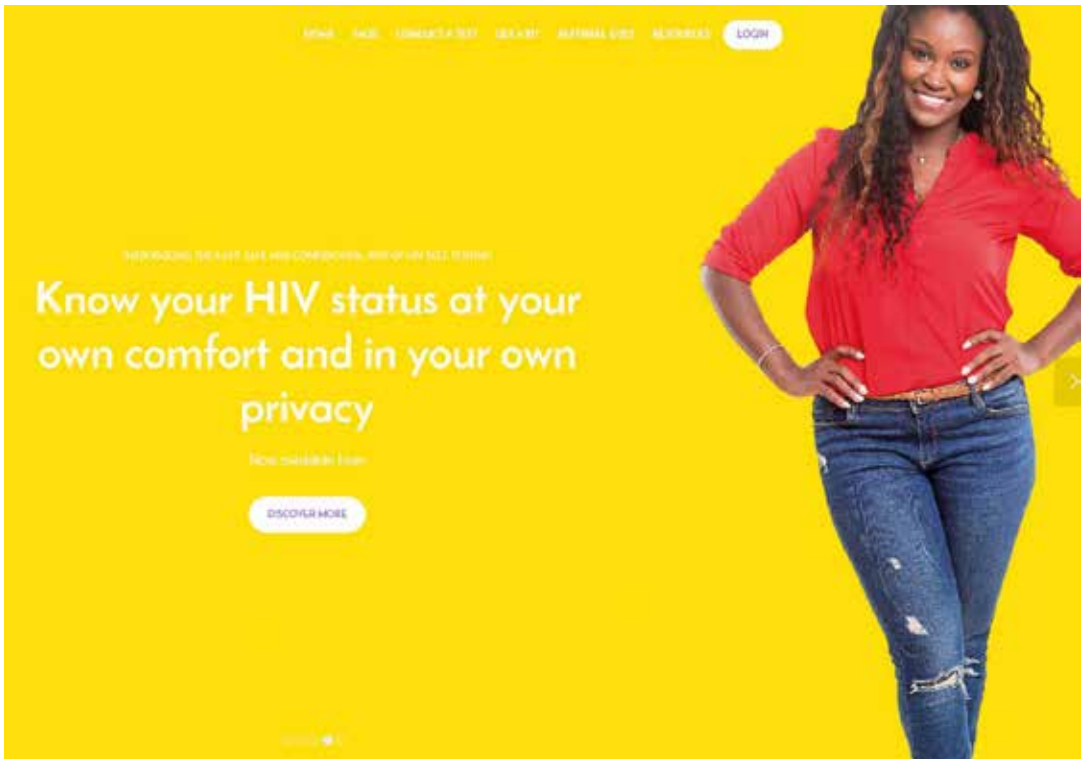
On 27 June 2017, a Charitable Support Agreement between the Bill & Melinda Gates Foundation and OraSure Technologies Inc was announced to lower the cost of the OraQuick HIV Self-Test for public-sector buyers in 50 low-income / high-burden countries. The funding to enable a more affordable price ($2.00 ex-works) will consist of support payments tied to the volume of product sold and the reimbursement of certain related costs. The investment is part of the Bill & Melinda Gates programme-related investments (PRI) strategy, which aims to stimulate innovation driven by the private sector, encourage market-driven efficiencies and attract external capital to priority global-health and development initiatives that improve the lives of the world's most vulnerable people.

More information, including a list of eligible countries, can be found at http://www.orasure.com/products-infectious/products-infectious-oraquick-self-test.asp.

Since December 2016, HIVST kits have become formally available in the private sector in select middle-income countries including Brazil, Kenya and South Africa. Several manufacturers view the private sector as an opportunity to introduce their products while the public-sector market develops, yielding important consumer insights and market experience (see Box 6). Most products are sold to consumers at prices ranging from approximately US$ 8.00 – US$ 16.00 at selected pharmacies and through online sales.

Box 6. PRIVATE-SECTOR EXPERIENCES WITH HIVST IN LOW AND MIDDLE- INCOME COUNTRIES

Following the May 2017 release of the Kenyan guidelines on how to implement HIVST, as of June 2017, four HIVST kits have entered the private sector in Kenya. Currently, all products are available in a limited number of pharmacies as part of a pilot programme led by the Pharmaceutical Society of Kenya. Expanded availability is expected through 2017.



Source: NASCOP Kenya; www.besure.co.ke

HIVST kits are also sold in the private sector in South Africa. In May 2017, the BioSURE HIV Self-Test was launched in South Africa; available as a single kit, in packs with multiple tests, and through subscription services to facilitate repeat HIV testing. In addition, Atomo Diagnostics is selling its HIV self-test, i-Test, in South African pharmacies.

Box 7. UNDERSTANDING HIVST COSTS AND COST EFFECTIVENESS

Much of the discussion around HIVST has focused on the unit cost of the kit, rather than overall investments required for HIVST service delivery. While reductions in the kit's unit price will have an impact on HIVST service-delivery costs, other costs, including supply-chain margins, human resources, overheads, and patient-level costs will also play a role. The impact of these factors can be seen in the health system perspective on the costs of standard HIV testing, which have a median cost (US$ 13, range: US$2-US$ 147) per person tested in LMICs [32], despite relatively cheaper unit prices for test kits, compared to HIVST.

The narrow focus on health-system costs, however, obscures the direct and indirect user costs which that individuals bear when accessing existing HIV testing options. If direct and indirect patient-level costs are included, the overall societal cost of testing increases substantially. For example, in Malawi, where a recent analysis estimated facility-based testing costs of US$ 7.53- US$ 10.57 per person tested, the addition of patient-level costs increased the overall costs per person tested to US$ 11.84 [33]. These patient-level costs can vary substantially by gender, further hindering access to HIV testing among groups that are already difficult to reach, such as men. The gendered costs of HIV testing were highlighted in an analysis from Malawi, where women reported user costs of US$ 1.84 to access testing, versus US$ 3.81 for men. Men's costs for accessing testing represent 154 per cent of the average daily wage in Malawi [32], and a substantial barrier to uptake of HTS testing.

Evidence suggests that HIVST may reduce these patient-level costs for both men and women. Data from Malawi comparing facility-based HIV testing with community-based HIVST found that while provider-level costs per person tested were similar between the two models, costs to patients were US$ 2.93 (95 per cent CI: US$ 1.90-3.96) lower among those testing with HIVST compared to professional-use rapid RDTs [33]. These societal-level cost savings for clients testing with HIVST versus facility-based HTS persisted through the first year on ART for those testing positive [34].

In addition to HIVST's cost-savings for patients and mitigation of financial barriers to testing, modelled data has also suggested the potential cost-effectiveness of HIVST, resulting in cost savings to the health system in LMICs, and modest health gains, relative to professional use testing alone [35]. More recent modelling data from

Zimbabwe suggests that HIVST may be an effective strategy in reaching populations that have been under-served by traditional HIV testing infrastructure, averting between 1200 and 4500 new HIV infections per year depending on the distribution strategy adopted [36]. While the analysis showed that where awareness of HIV status is high, HIVST may not be cost-effective from a health system perspective relative to current HIV testing at a threshold of $500/disability adjusted life years (DALY) averted, the model did suggest that achievement of the first UN 90 may not be possible without the addition of new strategies such as HIVST. Importantly, the analysis concluded that the cost-effectiveness was not substantially improved by a lower unit test cost (US$ 1.50 vs. US$ 4.80), but rather by introduction of HIVST into settings with lower awareness of HIV status, improvements in the linkage of HIV-negative individuals to prevention interventions following testing, and reductions in the costs of HIVST kit distribution [36]. While HIVST has already been shown to increase the coverage of HIV testing and reduce patient-level costs, efforts to reduce HIVST supply chain and distribution costs, improve linkages for both HIV-infected and uninfected individuals, and to better target self-testing to groups that need it most can continue to make HIVST an efficient and effective option for HIV control.

Manufacturing capacity

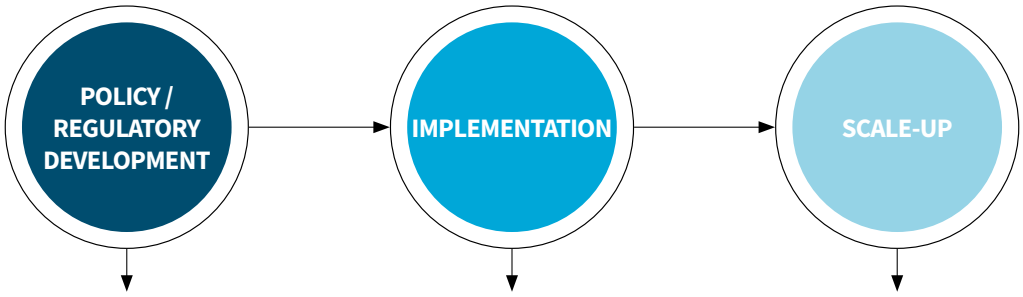
Currently, manufacturing capacity is not a barrier for meeting demand for HIV RDTs for self-testing, nor is it likely to become a barrier in the short- to medium-term. Supply sustainability strengthened in the last year with the entry of new fingerstick/whole blood-based RDT suppliers. Production lines for most professional-use RDTs have spare capacity that can be easily used to meet HIVST demand. Only minor modifications to manufacturing lines would be required for inclusion of tailored IFU and packaging. Furthermore, the automation of existing lines may further expand capacity with relatively minimal investment. Nevertheless, some coordination and/or aggregation of orders could be useful to provide manufacturers with greater ability to plan production runs and decrease lead times.

Enabling environment

Creating an enabling environment for HIVST involves the development of policies and regulations, but also needs to be facilitated through efficient implementation to lead to scale-up. As illustrated below (Figure 2), beyond having policies and regulations for HIVST approved in-country, they must also be operationalized in the form of guidelines and strategic plans.

Numerous steps are necessary to ease the implementation and scale-up of HIVST. These include transparent product registration processes, approved clinical sites and testing protocols for product evaluation for new products, clear distribution channels, supply chain and sales outlets in-country. Scale-up requires companies to build out quality-assured manufacturing facilities, to assure sustainable raw materials and to generate ongoing demand and effectively distribute products.

FIGURE 2.
Enabling environment pathway



- HIVST policy published
- Regulatory pathways approved
- Guidelines and operational plans published
- Approved clinical sites and testing protocols for product evaluation

- Transparent product registration
- Clear distribution channels
- Supply chain established
- Sales outlets available

- Capital equipment and manufacturing site(s) established
- GMP in place
- Sustainable source of raw materials
- Ongoing demand generation and distribution

GMP: Good manufacuring practices

Policy development and implementation

The HIVST policy landscape is changing rapidly. Following the release of the WHO guidelines in 2016, many countries have been quick to take up HIVST national policies and have already begun to implement various approaches. As of July 2017, 40 countries report that they have a policy supportive of HIVST (see Figure 3). This is more than twice as many policies reported in July 2016 [37]. Additionally, 48 other countries are planning to introduce HIVST policies; one third of which will be completed by 2018[1].

Despite these policy shifts, implementation of HIVST remains limited. Only 13 countries are actively implementing HIVST, the majority of which are high-income, and implementation in LMICs is largely in the context of operational research and within the STAR project, the first phase of which took place in three African countries (Malawi, Zimbabwe and the Zambia). Increasing implementation in additional countries will require donor investments from Unitaid, PEPFAR, and the Global Fund, as well as WHO's continued support to fully operationalize country policies. See Box 8 for Viet Nam's experience in developing HIVST policy.

[1] Source: WHO Country Intelligence Database, HIVST.org policy reporting and tracking and Global AIDS Monitoring, 7 July 2017

Box 8. WORKING AGGRESSIVELY TOWARDS DEVELOPING AN HIVST POLICY IN VIET NAM

The government of Viet Nam is working towards achieving the global targets of 90-90-90. Realizing that it would be impossible to achieve the first "90" with conventional facility-based HIV testing services, the Ministry of Health began piloting HIVST in selected provinces in 2016 with support from WHO.

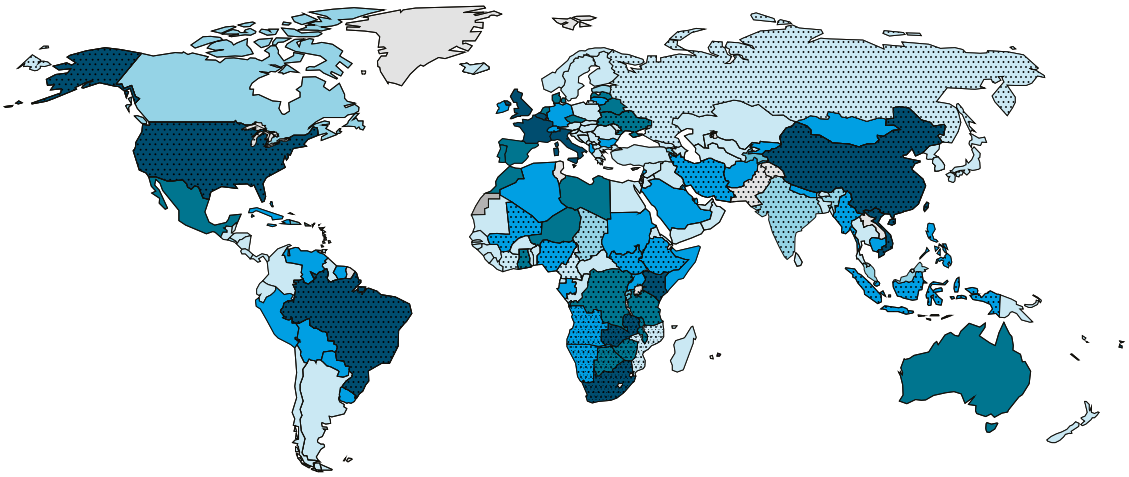
The results from these country-led pilots demonstrated that HIVST was an effective and efficient approach to reaching "unreached" key populations who were hesitant to access health-testing services at facilities. For example, between January and May 2017, in two provinces (Can Tho and Thai Nguyen), 805 people with high HIV risk received HIV testing through HIVST or lay providers. Overall, 45 were found to have HIV reactive results; 43/45 (95.6 per cent) were confirmed HIV positive (one had false positive and one had not yet confirmed); 39/43 (91 per cent) received ART. Among tested clients, 46 per cent were first-time testers.

Based on the results from these pilots, Viet Nam updated the guidelines to include lay provider testing and HIVST and is now rolling out both. As of May 2017, the new guidelines were officially approved and will be released later in the year.

Source: Personal communication, Dr Van Nguyen, WHO Viet Nam, 2017

FIGURE 3.

Countries with supportive or planned HIVST policies, as of July 2017



- Policy on HIVST implemented
- Policy on HIVST but still not implemented
- Policy on HIVST in development
- No policy
- Unknown
- No data reported
- Fast-Track countries
- Not applicable

Data Source: World Health Organization
Map Production: Information Evidence and Research (IER) World Health Organization

Countries with a supportive HIVST policies in place (n=40): Australia, Belarus, Belgium, Botswana, Brazil, Burundi, China, Czech Republic, Democratic Republic of the Congo, Denmark, France, Ghana, Italy, Kenya, Kiribati, Lao People's Democratic Republic, Latvia, Lebanon, Lesotho, Libya, Luxembourg, Malawi, Malta, Mexico, Monaco, Morocco, Netherlands, Niger, Portugal, Republic of Moldova, Rwanda, South Africa, Spain, Ukraine, United Kingdom, United Republic of Tanzania, United States of America, Viet Nam, Zambia and Zimbabwe.

Supportive HIVST policies under development (n=48): Afghanistan, Albania, Algeria, Angola, Armenia, Bahamas, Bahrain, Benin, Bolivia, Bulgaria, Cambodia, Cook Islands, Cuba, Dominica, Ethiopia, Fiji, Gabon, Germany, Haiti, Indonesia, Iran, Ireland, Kosovo, Kuwait, Kyrgyzstan, Lithuania, Mali, Mauritius, Mongolia, Myanmar, Namibia, Nepal, Nigeria, Niue, Paraguay, Peru, Philippines, Saudi Arabia, Singapore, Somalia, South Sudan, Sudan, Suriname, Swaziland, Switzerland, Uganda, Uruguay and Venezuela.

Approval and regulatory pathways in developing markets

The establishment of transparent approval channels and regulatory pathways is critical to enacting policies and enabling implementation and scale-up of HIVST. Known and consistent regulatory pathways bring more certainty to the market; this, in turn, enables manufacturers to bring products to market efficiently and at lower cost. In resource-limited settings, regulatory pathways, especially for IVDs are often opaque, costly, time-consuming, and lengthy. However, through the work of such organizations as the Pan-African Harmonization Working Party, efforts to rationalize regulation across the continent are underway [38].

International approval pathways

Many countries, particularly LMICs, use evaluations and approvals by WHO, the United States Agency for International Development (USAID), the United States Centers for Disease Control and Prevention (CDC), and stringent regulatory authorities[1] to guide local decisions in the absence of a national mechanism or national regulation of IVDs. The procurement policies of main international funders for HIV programmes (the Global Fund, PEPFAR, and Unitaid) require IVDs to be manufactured according to the applicable International Organization for Standardization (ISO), or equivalent standards, and for the IVD to be stringently reviewed and approved. In addition, as detailed earlier in this report, the ERPD provides expert recommendations on the use of needed IVDs that have not yet obtained stringent regulatory approval or WHO prequalification, leading to temporary eligibility for procurement by main donor institutions. 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/.

Similar to approvals from stringent regulatory authorities, WHO prequalification of an HIV RDT for self-testing involves an assessment of a product dossier that contains comprehensive information - provided by the manufacturer - that supports safety and performance, and requires an on-site inspection to evaluate manufacturing quality and risk management [39]. Currently one product for HIVST has been prequalified, see: http://www.who.int/diagnostics_laboratory/evaluations/170720_prequalified_product_list.pdf?ua=1. For details on the prequalification criteria for HIVST kits, see the WHO Technical Specification: http://apps.who.int/iris/bitstream/10665/251857/1/9789241511742-eng.pdf?ua=1.

[1] Stringent regulatory authority refers to founding members of the GHTF, including the regulatory authorities from Australia, Canada, the European Union, Japan and the United States of America.

Country-level regulatory approval challenges for LMICs

The WHO Prequalification Programme clarified the approval pathways for donor funded programmes and now focus is shifting toward country-level approval and regulatory processes. While many countries have developed or are developing HIVST policies, the lack of clarity regarding the regulatory environment for IVDs in most LMICs has slowed market entry there. In some settings, multiple agencies have overlapping mandates; in others, there is a complete absence of any authority to regulate such devices. Still others lack the laboratory capacity to evaluate products requesting regulatory approval. In addition to recognizing the assessment work of international bodies, such as those noted above, some countries also have national-level product evaluation and approval requirements, e.g. to qualify for product licensing and registration.

Several manufacturers have noted that the unclear regulatory environment in target markets is a key barrier. Some manufacturers are unwilling to undertake expensive registration processes without assurance that requirements will not change as pathways clarify, requiring new approvals. Others are not pursuing, or are waiting to pursue, registration because regulatory systems are currently under revision; and they plan to delay registration until revisions are final. Finally, several manufacturers in the HIVST market are relatively small companies with minimal experience in LMICs. Given their lack of experience, these manufacturers are seeking partnerships to facilitate their registration. In all instances, unclear approval pathways are delaying market entry presenting a significant threat to market development.

Box 9. SOUTH AFRICA'S PROGRESS TOWARDS FULL SCALE HIVST IMPLEMENTATION

In 2016, South Africa made significant progress in moving towards full scale HIVST implementation. The main barriers for the introduction of HIVST in the South African market were: (i) an undefined regulatory landscape for products, (ii) lack of WHO prequalified HIVST kits available, (iii) a lack of guidance from both a national and global perspective. However, with the release of the WHO's Guidelines on HIVST in December 2016, HIVST became more widely accepted in South Africa.

Also in December 2016, the South African Pharmacy Council lifted the ban on the sale of HIVST kits by pharmacists. The validation status and quality of emerging products were largely unknown. This prompted the National Department of Health (NDOH) and groups such as the Southern African HIV Clinicians Society (SAHCS) to step up the provision of guidelines for the industry in-country. The SAHCS spearheaded the formation of a technical working group that subsequently put together recommended guidelines for the NDOH for HIVST [40]. The guidelines were released in May 2017. Additionally, with a HIVST kit now WHO prequalified, implementation and scale-up of HIVST will likely begin in South Africa.

Photo: Mohammed Majam

Source: Personal communication, Mohammed Majam, WRHI, June 2017.

Global HIVST demand

Established demand

Demand in high- income countries

Between July 2012 and June 2017, approximately 1.35 to 1.42 million HIV RDTs for self-testing were sold in the US and Europe. The majority of these sales have been in the USA, where OraSure has sold approximately 1.1 million OraQuick® In-Home HIV Test kits[1], primarily through Internet and over-the-counter pharmacy sales during this period. The remainder of tests were sold in Europe after the first products were approved in 2015.

Source: Laure Poignant

[1] This is an estimate is based on OraSure's public reports from 2012 to present, divided by the estimated cost to distributers (US$ 28.00). It also factors in publicly available procurement reports, as well as reports from contacts with past and ongoing implementation projects.

Demand in LMICs

With an increasing evidence base, WHO recommendations , a WHO prequalified HIVST kit, and an increasing number of supportive policies, public-sector demand for HIVST is increasing. Based on a review of Unitaid investments, PEPFAR and Global Fund concept notes, it is expected that major donors will finance the procurement of at least 4 million HIVST kits between July 2017 and the end of 2018. This estimate may be conservative as it does not include an additional 20 LMICs that have indicated that they will include HIVST in activities, but have not yet finalized budgets and volumes.

Major donors supporting the market include:

- Unitaid, since 2015, has supported the largest HIVST implementation project in Malawi, Zambia and Zimbabwe. It will now add additional countries, including Lesotho, South Africa and Swaziland. As of June 2017, the STAR consortium had procured 732,422 RDTs for HIVST. STAR will procure approximately 4.7 million tests over the course of the project. In addition, a number of other HIVST grants are to be submitted to the Unitaid board to cover new areas where catalytic efforts are warranted to enable future scale-up.

- The Global Fund and PEPFAR agencies will be supporting HIVST programmatic implementation and operational research across various countries in the Americas, Africa, Asia and Europe. Many of the approaches focus on ways to reach men, young people (< 30 years), key populations and the partners of people with HIV. Procurement of RDTs for self-testing is planned to support these implementation studies. Based on the success of early implementation, further expansion of Global Fund and PEPFAR procurement is expected.

- The Bill & Melinda Gates Foundation supported a number of research studies as well as the negotiation and financing of a major price decrease for the OraQuick® HIV Self Test. The price decrease should significantly increase demand for HIVST amongst public-sector buyers.

In addition to the public-sector market, formal private-sector markets have begun to emerge in middle-income countries, most notably in Kenya and South Africa. The potential for consumer demand through the private sector in LMICs is promising, but the potential for scale is largely unknown. With the exception of recent investments from CIFF, little investment has been made to date to explore the possibility of the sector.

Understanding consumer preferences on blood-based and oral fluid-based HIVST

Depending on the user group, preferences for fingerprick/whole blood-based and oral-fluid-based HIVST kits vary. The preference for specimen type on the part of the end user depends on the type of population, setting, behavioural characteristics and availability of products. Often user preferences for oral self-tests are because users see the process as painless, easy, and less invasive [43]. However, for others, self-tests that use blood are preferred because they are considered to be more reliable or accurate [44]. While preferences do vary across populations, studies among people who inject drugs may be most likely to prefer a blood-based self-test [45].

Overall, while some users will have strong preferences, having both blood and oral options for HIVST will likely reach a variety of people who may not test otherwise.

It is currently unclear how consumer preference, particularly those for oral fluid or blood-based HIV RDTs for self-testing, will impact the market. Further research is needed to understand user preferences, as well as how these preferences might impact the market. See Box 10, below, for an example of building evidence to generate demand for HIVST.

Box 10. BUILDING EVIDENCE TO GENERATE DEMAND

The STAR project has substantially contributed to the development of the HIVST market in sub-Saharan Africa, by demonstrating high acceptability and effectiveness of several HIVST distribution strategies. These include: rural door-to-door distribution by lay community workers; peer-distribution with female sex workers; reaching men at workplaces; use of HIVST as part of demand creation for voluntary medical male circumcision (VMMC); increasing efficiency and testing uptake among clients presenting at health facilities through facility-based HIVST distribution; and reaching sexual partners of index PLHIV and other priority groups through secondary distribution of HIVST kits.

In Zimbabwe, where all of these distribution models were implemented, HIVST was able to substantially increase HIV testing coverage in communities previously not reached. Testing coverage among men and young people in the project areas increased by 28 and 38 per cent respectively, with a significant proportion of those using self-testing (23 per cent) being first-time testers. Linkage to care after self-testing was very high, with 80 per cent of reactive male self-testers in Zimbabwe initiating HIV treatment, compared to 51 per cent among men who received reactive tests through provider-delivered testing. In Zimbabwe, HIVST also demonstrated increasing uptake of HIV prevention services among HIV negative self-testers; preliminary results have demonstrated the impact of HIVST on increased uptake of VMMC among men, which has resulted in the national VMMC programme considering making HIVST an essential component of VMMC demand creation and service delivery. Based on the successes of the STAR Project, the Zimbabwean government became very supportive of HIVST, with policy and guidelines established. The Ministry of Health is interested in seeing the speed of HIVST scale-up by integrating it into existing national systems. As a result of this support, Zimbabwe included procurement of HIVST kits into their Global Fund funding request, HIVST has been included in the 2017 PEPFAR Country Operational Plan request, and there are plans to include HIVST with government procurement.

Source: Personal communication Karin Hatzold, 27 June 2017.

Potential demand estimates for priority developing markets

PSI, in partnership with Accenture Development Partners (ADP) and with the support of the Bill & Melinda Gates Foundation, analyzed the potential total size of the HIVST market to highlight how the market may develop and illustrate the impact of different investment and distribution strategies. The analysis included nine high burden countries in Africa, including Kenya, Malawi, Mozambique, Nigeria, South Africa, Tanzania, Uganda, Zambia, and Zimbabwe. Together, these countries represent approximately 50 per cent of the global HIV burden. In 2015, these countries tested approximately 48 million adults for HIV [46].

Key findings from this analysis showed that:

- With investments to modify currently unfavourable market conditions, the HIVST market can grow to represent a significant portion of HIV testing;
- Conservative estimates project that if donors and countries support HIVST, by 2020 the estimated market-size could be at least 3.3 – 5.7 million HIVST kits per year in the nine countries analysed;
- The most likely avenues for distribution include community-based testing channels and private-sector pharmacies; and
- Increasing the testing frequency of key populations may also be a promising way to grow the market. Upcoming data evaluating the use of HIVST to increase the efficiency of facility-based testing could also drastically increase the potential market size.

Because the HIVST market is still nascent, many products are still under development, and estimates of the size of the market have considerable uncertainty and limitations. A full description of the limitations, assumptions and methodology are available in PSI's report: "Expanding Access to HIV Self-Testing: A Market Development Approach" [46].

TABLE 4.

Market size estimates by distribution channel and level of investment.

Distribution Channel	Conservative Scenario (million tests)	Moderate Scenario (million tests)
Community-based channels	2.4 – 3.5	4.6 – 7.0
Private-sector pharmacy	-	3.3 – 4.3
Facility-based testing (excluding ANC)	-	1.2 – 1.7
Secondary distribution at ANC	-	0.7 – 0.8
Secondary distribution in facility-based	-	0.1 – 0.1
Key populations	0.8 – 2.1	0.8 – 2.1
TOTAL	**3.3 – 5.7**	**11.3 – 15.34**

Conclusion

Achieving the first 90 – diagnosis of 90 per cent of all PLHIV by 2020 – is of paramount importance to ending HIV/AIDS. If we are to reach the remaining 30 per cent PLHIV who still don't know their status [10], HIVST will need to be scaled up and integrated as part of the HIV response.

Since the release of the WHO guidelines, and a WHO prequalified HIVST kit, global and national policies have started to become clear, and implementation through public and private sectors is increasing across a variety of settings. Such increases have stimulated shifts in demand; with at least 4 million HIVST kits to be procured with funding from major donors between July 2017 and the end of 2018. The market appears to be scaling at a rate that is consistent with previous estimates suggesting demand for HIVST from public-sector buyers of at least 3.3 – 5.7 million kits per year across the nine highest-burden countries in Africa. To continue the momentum in HIVST a number of key considerations will need to be addressed by various players in the market.

Key considerations for countries, national programmes and regional bodies

- Following the WHO guidelines, countries and programmes should include HIVST as an approach to implementing HIV testing services, and consider how it can contribute to achieving national testing targets; particularly amongst populations with low testing uptake, high incidence, prevalence and risk of infection. These decisions should be reflected in national policies and strategies and then inform demand forecasts and advance implementation planning. This should include plans for establishment of strategies that further optimize linkages, as recommended by WHO for existing testing services.

- Governments should adopt clear and streamlined HIVST regulations and registration mechanisms to ensure that products meet quality assurance standards while also minimizing the costs and timelines associated with registration. Regulations, guidelines and operational plans should be published to assure transparency.

- In order to facilitate uptake and implement of HIVST, countries should leverage the work done by the WHO prequalification programme and the ERPD and consider this latter as a prerequisite for in-country registration of product. Additionally, countries should ensure that in-country validation studies, if required, are facilitated by the availability of pre-approved testing sites and protocols. Such studies should not be onerous or duplicative and fees should be minimized.

- National programmes should carefully consider product selection and should take actions to improve the diversity of supply. Given that the market is still nascent and evolving, countries should avoid locking in a single supplier. Furthermore, HIVSTs are highly differentiated products, which employ different specimen types, have varying product designs, test generations, time to results, etc. The degree to which these factors influence consumer demand is unknown; however, it is likely that across a large population of users some segments will prefer different products.

Key considerations for donors

- With WHO HIVST recommendations and a WHO prequalified HIVST product now in place, programmes should move from research to implementation and scale-up. While there are still operational research questions on how to optimize HIVST across settings, populations, and delivery methods, investigation of these questions should be nested within national-programme level approaches and focused on achieving public health impact, scale and relevant cost-effectiveness thresholds from LMICs.

- Donors should continue to support systems at the global level that ensure quality of required products, including WHO prequalification, ERPD and regional harmonization efforts. Where possible, donors should exert influence to strengthen in-country regulatory processes to block substandard tests while also minimizing the barriers to quality-assured products. Without such efforts, it is possible that a market for low-quality tests will develop in the private sector or in countries that transition from donor support.

- Donors should continue to support studies that will enable countries to integrate HIVST products into their national systems, as well as consider ways to incentivise manufacturers to innovate and improve their products.

- When supporting programmes or market interventions, donors should consider supporting the selection of multiple products that meet quality standards. This will support continued product development and innovation, increase competition and lead to a stronger and more diverse supply base.

- The role of the private sector is yet to be understood. CIFF is investing in understanding the potential of the private sector in Kenya and additional investments in other middle-income country markets could speed the development of the market by identifying and overcoming key constraints.

- Given flat or reduced donor budgets for HIV testing, it is critical that donor agencies continue to coordinate, as is now the case with Unitaid, the Bill & Melinda Gates Foundation, CIFF, Global Fund and PEPFAR, to ensure that HIVST products are accessible and affordable in LMICs.

Key considerations for manufacturers

- Manufacturers should pursue approvals through global mechanisms, including ERPD and WHO prequalification. These approvals demonstrate a clear commitment to quality and are necessary for donor-funded procurement. Moreover, manufacturers will eventually enjoy the benefit of a simplified pathway if WHO prequalification is a consideration for in-country registration.

- Existing HIVST products rely heavily on the adaptation of existing professional use HIV RDTs. However, there is significant need to further optimize existing HIV RDTs and corresponding IFUs for self-testing. In parallel to pursuing approvals from ERPD, WHO prequalification and in-country regulatory bodies, manufacturers, should consider plans to optimize and further improve HIVST kits. This could lead to higher performing tests, greater uptake, and frequency of testing among users and thus a greater market size.

- Manufacturers engaged in developing HIVST products may also generate information and experiences that spill over into the professional-use market, such as improved usability of test kits, fewer test kit components, easy-to-read IFUs, and other innovations. For some manufacturers, there may be an incentive or possibility to leverage the professional-use market within their HIVST market strategy.

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Annex 1

Summary of WHO prequalified or Global Fund approved HIV RDTs for professional use

TABLE 1.A

Summary table of WHO prequalified HIV RDTs for professional use (oral fluid)

Assay name (manufacturer)	Sensitivity*	Specificity*	Approval status
DPP® HIV 1/2 Assay (Chembio Diagnostic Systems Inc., USA)	100%	99.9%	**WHO PQ**
OraQuick® HIV 1/2 Rapid Antibody Test (OraSure Technologies Inc., USA)	99.1%	99.8%	**WHO PQ**

* sensitivity and specificity estimates for oral fluid as a specimen type
PQ: prequalification

TABLE 2.A

Summary table of WHO prequalified or Global Fund approved HIV RDTs for professional use (fingerstick/whole blood)

Assay name (manufacturer)	Sensitivity*	Specificity*	Approval status
ABON™ HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device (ABON Biopharm (Hangzhou) Co. Ltd, China)	100%	99.7%	**WHO PQ**
Alere Determine HIV-1/2 (Alere Medical Co. Ltd, Japan)	100%	99.4%	**WHO PQ**
Alere HIV Combo (Alere Medical Co. Ltd, Japan)	100%	99.72%	**CE marked**
Anti-HIV 1/2 (Turk Lab, Turkey)	100%	100%	**CE marked**
Diagnostic kit for HIV (1+2) antibody (colloidal gold) V2	100%	100%	**WHO PQ**
DIAQUICK HIV 1&2 Ab Cassette (DIALAB GmbH, Austria)	100%	100%	**CE marked**

Assay name (manufacturer)	99.8%	Specificity*	WHO PQ
First Response™ HIV 1-2-0 Card Test (Premier Medical Corporation, Nani Daman, India)	100%	98.8%	**CE marked**
Genie Fast HIV 1/2 (Bio-Rad Laboratories, Marnes La Coquette, France and Steenvoorde, France)	100%	99.9%	**CE marked**
Hexagon HIV (Human Gesellschaft für Biochemica und Diagnostica mbH Germany)	100%	99.9%	**CE marked**
HIV 1/2 STAT-PAK® Dipstick (Chembio Diagnostic Systems Inc., USA)	100%	99.7%	**WHO PQ**
HIV 1/2 STAT-PAK™ (Chembio Diagnostic Systems Inc., USA)	99.3%	100%	**WHO PQ**
INSTI HIV-1/HIV-2 Antibody Test (BioLytical Laboratories Inc., Canada)	100%	99.7%	**WHO PQ**
Multispot HIV-1/HIV-2 Rapid Test (Bio-Rad Laboratories, Marnes La Coquette, France and Steenvoorde, France)	100%	99.3%	**FDA/ PMA**
Multisure HIV Rapid Test (MP Biomedicals Asia Pacific, Singapore)	100%	99.12%	**CE marked**
ONE STEP Anti-HIV(1&2) Test (InTec PRODUCTS INC., Haicang, Xiamen, China)	99.8%	99.23%	**CE marked**
Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device) Beijing Wantai Biological Pharmacy Enterprise Co. Ltd, China)	100%	98.48%	**WHO PQ**
SD Bioline HIV Ag/Ab Combo (Standard Diagnostics Inc., Republic of Korea)	100%	99.1%	**WHO PQ**
SD BIOLINE HIV/Syphilis Duo (Standard Diagnostics Inc., Republic of Korea)	100%	99.5%	**WHO PQ**
SD BIOLINE HIV-1/2 3.0 (Standard Diagnostics Inc., Republic of Korea)	99.8%	99.9%	**WHO PQ**
SURE CHECK® HIV 1/2 Assay (Chembio Diagnostic Systems Inc., USA)	99.8%	99.9%	**WHO PQ**
Uni-Gold™ HIV (Trinity Biotech Manufacturing Ltd, Ireland)	99.4%	99.9%	**WHO PQ**
VIKIA HIV 1/2 (bioMérieux SA, France)	100%	99.9%	**WHO PQ**

CE: European Conformity; FDA: United States Food and Drug Administration; PMA: Pre-market approval; PQ: prequalification

Annex 2

Specification information for HIV self-test products in the market

Action![1]

Product specification	
Commercial name (trade mark)	Action!
Professional test basis (Commercial professional use name-trademark)	N/A
HIVST product photo	
Approval status for professional use product	Approved as self-test only
Company	Orangelife Comércio e Indústria LTDA
Manufacturing site	Brazil
Type of technology	Immunochromatography
Generation (2nd, 3rd or 4th)	3rd
Antigen type	p24, gp41, gp36
Output	Qualitative immunoassay, HIV- 1/2 antibody detection
HIVST sensitivity	99.9%
HIVST specificity	99.9%
HIVST invalid rate	N/A
Sample type	Whole blood
Capacity	Single specimen – one-time use
Volume of sample required	10 µL

Product specification	
Volume of buffer required	3 drops of buffer (~100µL)
Time to result	Do not read before 10 minutes
Read window	Do not read after 20 minutes
Protocol complexity – steps required[1]	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 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, IFU and HIVST 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.
Controls	The test has an internal control line to indicate that specimen has well migrated.
Approval status for HIVST product	Approved by Anvisa/Brazil (National Sanitary Surveillance Agency)
Pricing (US$/per test)	US$ 14 (free-on-board)
Sale mechanism (directly to consumers/ intermediary marketing/both)	Both
Minimum order size for intermediary marketing	1,000 units
Additional details	Test kit has not been evaluated formally among people using ART drugs for prevention (e.g. PrEP or PEP). Anticoagulants such as heparin, EDTA, and citrate do not affect the result. Relevant interferons known as hemolytic samples, rheumatoid factor, icteric, haemolysed, and lipemic samples may impair test results. Website: http://testeaction.com.br/

[1] Note this product is currently only available in Brazil

atomo HIV Self-Test[1]

Product specification	
Commercial name (trade mark)	Atomo HIV Self Test Sold as i-test (South African markets only)
Professional test basis (Commercial professional use name-trademark) **HIVST product photo**	AtomoRapidTM HIV (1&2)
Approval status for professional use product	CE mark[2]
Company	Atomo Diagnostics
Manufacturing site	Australia
Type of technology	Immunochromatography (lateral flow)
Generation (2nd, 3rd or 4th)	3rd
Antigen type	Recombinant proteins for HIV-1 and HIV-2; this allows detection of IgM and IgG antibodies.
Output	Qualitative immunoassay, HIV-1/2 antibody detection
HIVST sensitivity	99.7%
HIVST specificity	99.7%
HIVST 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]	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 3 drops of buffer solution 5. Interpret test result
Shelf life of test kit	24 months
Storage requirements	Store between 2 – 30°C; do not store in direct sunlight

[1] Note this product is currently only available in South Africa and Kenya

Product specification	
Test kit components	Box containing integrated test device, buffer solution, IFU, 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 (e.g. haemophilia).
Controls	Test has internal control (control line) to indicate sample has migrated Control specimens (e.g. test kit controls) are available but sold separately
Approval status for HIVST product	CE mark pending. WHO PQ, dossier submitted in 2016. National regulatory approval for sale in Kenya.
Pricing (US$/per test)	$3, volume dependent for public sector
Sale mechanism (directly to consumers/ intermediary marketing/both)	Both
Minimum order size for intermediary marketing	5,000 units
Additional details	Test kits have been evaluated formally among people taking ARV drugs for prevention (PrEP) although the current product does not make an intended use claim for people on PrEP. http://atomodiagnostics.com/products/atomo-hiv-self-test/

autotest VIH®

Product specification	
Commercial name (trade mark)	autotest VIH®
Professional test basis (Commercial professional use name-trademark)	SURE CHECK® HIV-1/2/STAT-VIEW® HIV-1/2 Assay
HIVST product photo	
Approvals for professional use product	CE, FDA, WHO PQ
Company	AAZ-LMB
Manufacturing site	Rungis Cedex, France
Type of technology	Immunochromatography (lateral flow)
Generation (2nd, 3rd or 4th)	3rd
Antigen type	Synthetic: gp36, gp41, gp120 Control line: Protein A
Output	Qualitative immunoassay, HIV-1/2 antibody detection
HIVST sensitivity	100%
HIVST specificity	99.8%
HIVST 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

Product specification	
Protocol complexity – steps require	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 results
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 IFU
Not included in test kit	Timer
Restrictions for use	Wash hands and ensure they are clean and dry before testing. Does 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.
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 (e.g. test kit controls) are available but sold separately
Approvals for HIVST product	CE
HIVST pricing (US$/per test)	US$ 22–28 is the recommended consumer price in Europe; US$ 8–15 for distributors and NGOs depending on format
Sale mechanism (directly to consumers/ intermediary marketing/both)	Both
Minimum order size for intermediary marketing	Varies according to packaging and IFU requirements, pricing and other factors, but generally several thousand units
Additional details	Test kit has been evaluated formally among people using ARV drugs for treatment and for prevention (e.g. PrEP or PEP); however, the current product does not make an intended use claim for people on PrEP or PEP. Website: www.autotest-vih.eu

BioSURE HIV Self Test (hardcase)/(softcase)

Product specification	
Commercial name (trade mark)	BioSURE HIV Self Test
Professional test basis	SURE CHECK® HIV-1/2/STAT-VIEW® HIV-1/2
HIVST product photo	
Approval status for professional use product	CE
Company	BioSure United Kingdom Ltd
Manufacturing site	United Kingdom
Type of technology	Immunochromatography (lateral flow)
Generation (2nd, 3rd or 4th)	2nd
Antigen type	Synthetic : gp36, gp41, gp120 Control line: Protein A
Output	Qualitative immunoassay, HIV-1/2 antibody detection
HIVST sensitivity	99.7%
HIVST specificity	99.9%
HIVST invalid rate	0.16%
Sample type	Whole blood
Capacity	Single specimen – one-time use
Volume of sample required	2.5 mL (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
Protocol complexity – steps required[1]	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 results

Product specification	
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), IFU booklet, integrated results reading booklet, disposal bag, 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 anti-retroviral therapy (ART).
Controls	Test has a control to indicate that human specimen has been added. Control specimens (e.g. test-kit controls) are available but sold separately.
Approval status for HIVST product	CE
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 (NHS)
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 (e.g. PrEP or PEP). Website: https://hivselftest.co.uk/

INSTI® HIV Self Test (box)

Product specification	
Commercial name (trade mark)	INSTI® HIV Self Test (Box)
Professional test basis (Commercial professional use name-trademark)	INSTI® HIV-1/HIV-2 Antibody test
HIVST product photo	
Approval status for professional use product	CE/FDA/Health Canada/WHO prequalification CLIA Complexity: waived for fingerstick whole blood and moderate for venous whole blood and plasma
Company	bioLytical Laboratories
Manufacturing site	Richmond, British Columbia, Canada
Type of technology	Immunofiltration (flow through)
Generation (2nd, 3rd or 4th)	3rd
Antigen type	gp41 and gp36 antigen Control: protein A
Output	Qualitative immunoassay, HIV-1/2 combined antibody detection
HIVST sensitivity	100%
HIVST specificity	99.80%
HIVST invalid rate	0%
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 5 minutes

Product specification	
Protocol complexity – steps required[2]	1. Remove cap of sample diluent 2. Remove lid from safety lancet and apply to finger 3. Collect sample (fingerprick) 4. Insert sample into sample diluent 5. Sequentially invert and pour sample diluent, colour developer and clarifying solution onto test device 6. Interpret test results
Shelf life of test kit	15 months
Storage requirements	Store at 15 - 30°C. The kit can be refrigerated (2-8°C) if required.
Test kit components	1 cardboard box containing test device, sample diluent, colour developer, clarifying solution, IFU, HIVST booklet, 1 sterile single-use lancet, 1 pipette, an adhesive bandage, and disposal bag
Not included in test kit	Not required
Restrictions of use	Not suitable for users who have a bleeding disorder Not suitable for users below the age of 18 Not suitable for users who are taking ARV drugs for prevention (e.g. PrEP or PEP) or treatment (i.e. ART) Not suitable for users who have participated in an HIV vaccine study.
Controls	Built in procedural control of protein A which detects the human IgG antibodies. Test kit quality controls available upon request.
Approval status for HIVST product	CE
Pricing (US$/per test)	US$ 33 is recommended consumer price in Europe. Pricing information for distributors and NGOs available upon request.
Sale mechanism (directly to consumers/ intermediary marketing/both)	Both
Minimum order size for intermediary marketing	N/A
Additional details	The test has not been formally tested on people who are on ART, either for treatment of infection or in PrEP programmes. http://biolytical.com/products/insti-hiv-self-test-box/

OraQuick® In-Home HIV Test

Product specification	
Commercial name (trade mark)	OraQuick® In-Home HIV Test
Professional test basis (Commercial professional use name-trademark)	OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test
IVST product photo	
Approvals for professional use product	FDA/CE
Company	OraSure Technologies Inc
Manufacturing site	Bethlehem, PA, USA
Type of technology	Immunochromatography (lateral flow)
Generation (2nd, 3rd or 4th)	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
HIVST sensitivity	FDA: 91.7% CE: 100%
HIVST specificity	FDA: 99.98% CE: 99.8%
HIVST invalid rate	FDA: 1.1% CE: 1.8%
HIVST invalid rate	0.1%
Sample type	Oral fluid
Capacity	Single specimen – one-time use
Volume of sample required	N/A
Volume of buffer required	1 mL
Time to result	Do not read before 20 minutes
Read window	Do not read after 40 minutes

Product specification	
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, IFU 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 12 years old. Operate at 15–37 °C.
Controls	Addition of procedural quality control (band appears when human specimen is added and sample has flown up the device)
Approvals for HIVST product	FDA Formal CE mark pending as product has not yet been launched in the EU
HIVST pricing (US$/per test)	US$ 40 recommended consumer price in the US; prices to public health 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	Detects HIV-1 seroconversion 2.5 days (95% CI: 1.2–3.8) later than CE marked enzyme immunoassay (EIA) Test kit has not been evaluated formally among people using ARV drugs for prevention (e.g. PrEP or PEP). Website: http://www.oraquick.com

OraQuick® HIV Self Test

Product specification	
Commercial name (trade mark)	OraQuick® HIV Self-Test
Professional test basis (Commercial professional use name-trademark)	OraQuick® Rapid HIV-1/2 Antibody Test
HIVST product photo	
Approvals for professional use product	WHO prequalification
Company	OraSure Technologies Inc
Manufacturing site	USA - assembled in Thailand
Type of technology	Immunochromatography (lateral flow)
Generation (2nd, 3rd or 4th)	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
HIVST sensitivity	100.0%*
HIVST specificity	99.1%*
HIVST invalid rate	N/A
Sample type	Oral fluid
Capacity	Single specimen – one-time use
Volume of sample required	N/A
Volume of buffer required	1 mL
Time to result	Do not read before 20 minutes
Read window	Do not read after 40 minutes
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

Product specification	
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 IFU
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 ART. Not for use in individuals less than 12 years old. Operate at 15–37 °C.
Controls	Test has a control to indicate that human specimen has been added. (i.e. band appears when human specimen is added). Control specimens (e.g. test-kit controls) are available but sold separately.
Approvals for HIVST product	WHO PQ
HIVST Pricing (US$/per test)	US$ 2 for 50 countries (pursuant to agreement with BMGF)
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 (e.g. PrEP or PEP)

* HIVST sensitivity and specificity is provided from the ERPD report. See WHO report for further information: http://www.who.int/diagnostics_laboratory/evaluations/pq-list/170720_final_amended_pqdx_0159_055_01_oraquick_hiv_self_test_v2.pdf?ua=1

Annex 3

Specification Information for HIV self-test products emerging in the market

Asanté™ HIV Self Test

Product specification	
Commercial name (trade mark)	Asanté™ HIV Self Test
Professional test basis (Commercial professional use name-trademark)	Asanté™ HIV-1/2 oral fluid Rapid Test
HIVST product photo	
Approval status for professional use product	None yet; anticipate submitting to WHO PQ in late 2017
Company	Sedia Biosciences Corporation
Manufacturing site	Portland, Oregon, USA
Type of technology	Lateral flow immunoassay
Generation (2nd, 3rd or 4th)	2nd
Antigen type	Recombinant gp41, p24-gp41 fusion protein, recombinant gp36
Output	Qualitative immunoassay, HIV-1/2 antibody detection
HIVST sensitivity	N/A
HIVST specificity	N/A
HIVST invalid rate	N/A
Sample type	Oral fluid or Blood/Serum/Plasma

Product specification	
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
Protocol complexity – steps required[1]	1. Collect sample (oral swab OR fingerprick) 2. Place sample into sample buffer tube, mix and remove swab or loop. 3. Drop test strip into sample buffer tube 4. Interpret test results visually or using handheld reader
Shelf life of test kit	Minimum 2 years
Storage requirements	Store at 2-30 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
Not included in test kit	Lancets, alcohol wipes, handheld reader (reader sold separately)
Restrictions for use	The product has not yet been evaluated among people using ARV for prevention (PrEP or PEP).
Controls	In development
Approval status for HIVST product	
Pricing (US$/per test)	Dependent on volumes and country of sale
Sale mechanism (directly to consumers/ intermediary marketing/both)	Direct to users in public health; sale through distributors in some countries
Minimum order size for intermediary marketing	50 units
Additional details	N/A

Aware™ HIV-1/2 OMT oral HIV Self Test

Product specification	
Commercial name (trade mark)	Aware™ HIV-1/2 OMT, oral HIV Self Test
Professional test basis (Commercial professional use name-trademark)	Aware™ HIV-1/2 OMT, oral HIV Rapid Test
HIVST product photo	
Approvals for professional use product	USAID waiver list
Company	Calypte Biomedical Corporation
Manufacturing site	Thailand
Type of technology	Immunochromatography (lateral flow)
Generation (2nd, 3rd or 4th)	2nd
Antigen type	gp36, gp41
Output	Qualitative immunoassay, HIV-1/2 antibody detection
HIVST sensitivity	N/A
HIVST specificity	N/A
HIVST invalid rate	N/A
Sample type	Oral fluid
Capacity	Single specimen – one time use
Volume of sample required	N/A
Volume of buffer required	180 to 500µL
Time to result	Do not read before 20 minutes
Protocol complexity – steps required	1. Insert test tube into stand and remove test cap 2. Collect specimen by swabbing gum lines 3. Transfer specimen to test tube containing buffer 4. Insert test strip into test tube, wait 20 minutes 5. Remove test strip and lay on IFU reference diagram 6. Interpret test result

Product specification	
Shelf life of test kit	18 months (unopened); 7 days (opened)
Storage requirements	Store between 2° to 30°C. Do not freeze. Do not store in direct sunlight
Test kit components	1 Test Kit Box (used as test tube stand) containing: • 1 instruction for use, • 1 capped test tube (containing 1mL of buffer), • 1 plastic pouch (containing 1 oral collection swab), • 1 foil pouch (containing 1 test strip and 1 desiccant)
Not included in test kit	Timer
Restrictions for use	Do not use this test after expiration date shown on box. Do not eat, drink or chew anything 10 minutes before testing Do not open pouch until ready to perform test Not intended for people with HIV-1/2 using ART. Keep away from small children.
Controls	Control specimens (e.g. test kit controls) are available but sold separately. All control specimens are derived from inactivated human plasma. None of the controls were designed to produce an invalid test result.
Approvals for HIVST product	WHO PQ and CE submissions pending
HIVST pricing (US$/per test)	Target price US$ 3.00 USD (gross), final price dependent upon order volume
Sale mechanism (directly to consumers/ intermediary marketing/both)	Both
Minimum order size for intermediary marketing	15,000 units
Additional details	Test is for screening purposes only. This test has not been formally evaluated among people using ARV for treatment or prevention of HIV (e.g. PrEP or PEP).

Exacto® HIV Screening Test

Product specification	
Commercial name (trade mark)	Exacto® HIV Screening Test
Professional Test Basis (Commercial professional use name-trademark)	Exacto® Pro Test HIV
HIVST product photo	
Approvals for professional use product	CE
Company	Biosynex Group
Manufacturing site	France
Type of technology	Immunochromatography (lateral flow)
Generation (2nd, 3rd or 4th)	2nd
Antigen type	Synthetic: gp41,gp36
Output	Qualitative immunoassay, HIV-1/2 antibody detection
HIVST sensitivity	N/A
HIVST specificity	N/A
HIVST invalid rate	N/A
Sample type	Whole blood
Capacity	Single specimen – one-time use
Volume of sample required	N/A
Volume of Buffer required	2 drops[1]
Time to result	Do not read before 10 minutes
Read window	Do not read after 20 minutes
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 result

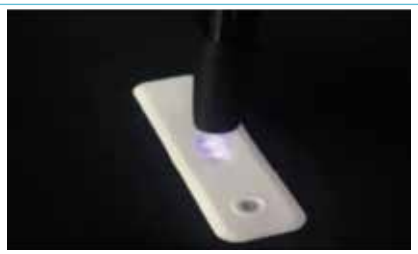
Product specification	
Shelf life of test kit	N/A
Storage requirements	2-30°C – do not store in direct sunlight or open foil packet until ready to use test
Test kit components	1 foil pouch with test cassette and desiccant, 1 buffer solution, 1 bandage, 1 alcohol-wipe, 1 sterile pad, 1 lancet and 1 inverted cup/capillary tube, IFU, 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 setting with 15-30°C
Controls	Test has a control to indicate that human specimen has been added. Control specimens (e.g. test-kit controls) are available but sold separately.
Approvals for HIVST product	CE mark pending
HIVST pricing (US$/per test)	Price to distributors and consumers not yet available.
Sale mechanism (directly to consumers/ intermediary marketing/both)	Sale mechanism (directly to consumers/ intermediary marketing/both)
Minimum order size for intermediary marketing	Minimum order size for intermediary marketing
Additional details	Sale mechanism (directly to consumers/ intermediary marketing/both) Minimum order size for intermediary marketing Validation study from CE mark study did not provide sensitivity and specificity but stated that 99.5% of participants obtained interpretable result and 98% of the results were interpreted correctly. Test kit has not been evaluated formally among people using ARV drugs for prevention (e.g. PrEP or PEP)

INSTI® HIV Self Test (pouch)

Product specification	
Commercial name (trade mark)	INSTI® HIV Self Test (Pouch)
Professional test basis (Commercial professional use name-trademark)	INSTI® HIV-1/HIV-2 Antibody test
HIVST product photo	
Approval status for professional use product	CE/FDA/Health Canada/WHO prequalification CLIA Complexity: waived for fingerstick whole blood and moderate for venous whole blood and plasma
Company	bioLytical Laboratories
Manufacturing site	Richmond, British Columbia, Canada
Type of technology	Immunofiltration (flow through)
Generation (2nd, 3rd or 4th)	3rd
Antigen type	gp41 and gp36 antigen Control: protein A
Output	Qualitative immunoassay, HIV-1/2 combined antibody detection
HIVST Sensitivity	99.8%
HIVST Specificity	99.5%
HIVST Invalid Rate	0%
Sample type	Whole blood
Capacity	Single specimen – one-time use
Volume of sample required	50 µL
Volume of Buffer required	1.5 mL 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 5 minutes

Product specification	
Protocol complexity – steps required	1. Remove cap of sample diluent 2. Remove lid from safety lancet and apply to finger 3. Collect sample (fingerprick) 4. Add one drop of sample into sample diluent 5. Sequentially invert and pour sample diluent, colour developer and clarifying solution onto test device 6. Interpret test results
Shelf life of test kit	15 months
Storage requirements	Store at 15 - 30°C. The kit can be refrigerated (2-8°C) if required.
Test kit components	1 pouch containing test device, sample diluent, colour developer, clarifying solution, IFU, 1 sterile single-use lancet, and an adhesive bandage
Not included in test kit	Not required
Restrictions of Use	Not suitable for users who have a bleeding disorder Not suitable for users below the age of 18 Not suitable for users who are taking ARV drugs for prevention (e.g. PrEP or PEP) or treatment (i.e. ART) Not suitable for users who have participated in an HIV vaccine study.
Controls	Built in procedural control of protein A which detects the human IgG antibodies. Test kit quality controls available upon request.
Approval status for HIVST product	CE mark, ERPD and WHO prequalification pending
Pricing (US$/per test)	$3.00 to distributors, governments and NGOs
Sale mechanism (directly to consumers/ intermediary marketing/both)	Both
Minimum order size for intermediary marketing	10,000
Additional Details	The test has not been formally tested on people who are on ARV drugs, either for treatment or prevention. http://biolytical.com/products/insti-hiv-self-test-pouch/

Rapid Test for HIV-1 Antibodies in Urine (Fluorescent Immunochromatographic Assay

Product specification	
Commercial name (trade mark)	To be determined
Professional test basis (Commercial professional use name-trademark)	Rapid Test for HIV-1 Antibodies in Urine (Fluorescent Immunochromatographic Assay)
HIVST product photo	
Approval status for professional use product	Under registration in China
Company	Beijing Wantai Biological Pharmacy Enterprise Co.,Ltd
Manufacturing site	Changping District, Beijing, China
Type of technology	Fluorescent immunochromatographic assay
Generation (2nd, 3rd or 4th)	3rd
Antigen type	Recombinant HIV-1 antigen, gp160 and gp41
Output	Qualitative fluorescence
HIVST sensitivity	N/A
HIVST specificity	N/A
HIVST invalid rate	N/A
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]	1. Collect urine sample 2. Add approximately 80µL 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

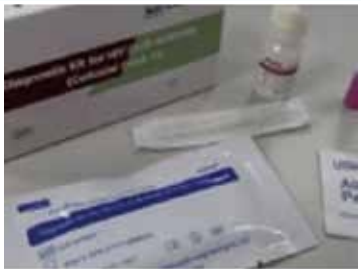
Product specification	
Test kit components	Test cassette in foil pouch with desiccant, buffer, UV-pen or other UV emitting device, urine collection cup
Not included in test kit	N/A
Restrictions for use	Only for detection of HIV-1; not for HIV-2
Controls	Integrated control-line. No separate quality controls are available.
Approval status for HIVST product	National regulatory approval in China pending
Pricing (US$/per test)	N/A
Sale mechanism (directly to consumers/ intermediary marketing/both)	Both
Minimum order size for intermediary marketing	N/A
Additional details	N/A

SURE CHECK® HIV Self Test

Product specifications	
Commercial name (trade mark) Professional Test Basis	SURE CHECK® HIV Self Test
(Commercial professional use name-trademark)	SURE CHECK® HIV-1/2
Approvals for professional use product	CE/FDA/WHO PQ approved for professional use CLIA Complexity: Waived for fingerstick and venous whole blood / Moderate for serum and plasma
Company	Chembio Diagnostic Systems Inc
Manufacturing site	Medford, NY, USA
Type of technology	Immunochromatographic (lateral flow)
Generation (2nd, 3rd or 4th)	2nd
Antigen type	Synthetic: gp36, gp41, gp120 Control line: protein A
Output	Qualitative immunoassay, HIV-1/2 antibody detection
HIVST sensitivity	N/A
HIVST specificity	N/A
HIVST invalid rate	N/A
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
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

Product specifications	
Shelf life of test kit	24 months from date of manufacture
Storage requirements	8 - 30°C – do not store in direct sunlight or open foil packet until ready to use test
Test kit components	1 foil pouch containing test barrel style cassette, buffer cap, desiccant packet, bandage, safety lancet, test stand
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.
Controls	Test has a control to indicate that human specimen has been added. Control specimens (e.g. test-kit controls) are available, but are sold separately.
Approvals for HIVST product	Planned CE and WHO PQ Two private-label versions of the product are CE-marked for self-testing in the EU (BioSURE HIV Self-Test and autotest VIH®)
HIVST 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 NGO's and funders or in-country through local distributors.
Minimum order size for intermediary marketing	To be determined
Additional Details	N/A

To be determined product

Product specification	
Commercial name (trade mark)	To be determined
Professional test basis (Commercial professional use name-trademark)	Diagnostic Kit for HIV(1+2) Antibody (Colloidal Gold) v2
HIVST product photo	
Approval status for professional use product	WHO PQ
Company	Shanghai Kehua Bio-engineering Co., Ltd
Manufacturing site	Shanghai, China
Type of technology	Immunochromatography test
Generation (2nd, 3rd or 4th)	3rd
Antigen type	Mammalian cell expression and DNA recombination technology
Output	Qualitative immunoassay, HIV-1/2 antibody detection
HIVST sensitivity	N/A
HIVST specificity	N/A
HIVST invalid rate	N/A
Sample type	Whole blood
Capacity	Single specimen – one-time use
Volume of sample required	40 µL
Volume of buffer required	50 µL
Time to result	Do not read before 15 minutes
Read window	Do not read after 25 minutes
Protocol complexity – steps required 1	1. Remove cap from lancet and apply to finger 2. Collect sample using pipette; fill until the blood reaches the second graduation (40ul) 3. Place sample into test device 4. Add drop of sample diluent vertically to the same area. 5. Interpret result.

Product specification	
Shelf life of test kit	18 months
Storage requirements	4-30°C
Test kit components	Test cassette, desiccant, diluent, safety lancet, alcohol pad, disposable transfer pipette
Not included in test kit	Timer
Restrictions for use	N/A
Controls	Test has an internal addition control to indicate buffer was added to the device (without specimen)
Approval status for HIVST product	N/A
Pricing (US$/per test)	US$ 1.2-1.5 per test (ex-works)
Sale mechanism (directly to consumers/ intermediary marketing/both)	Both
Minimum order size for intermediary marketing	0.22 million units
Additional details	N/A

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