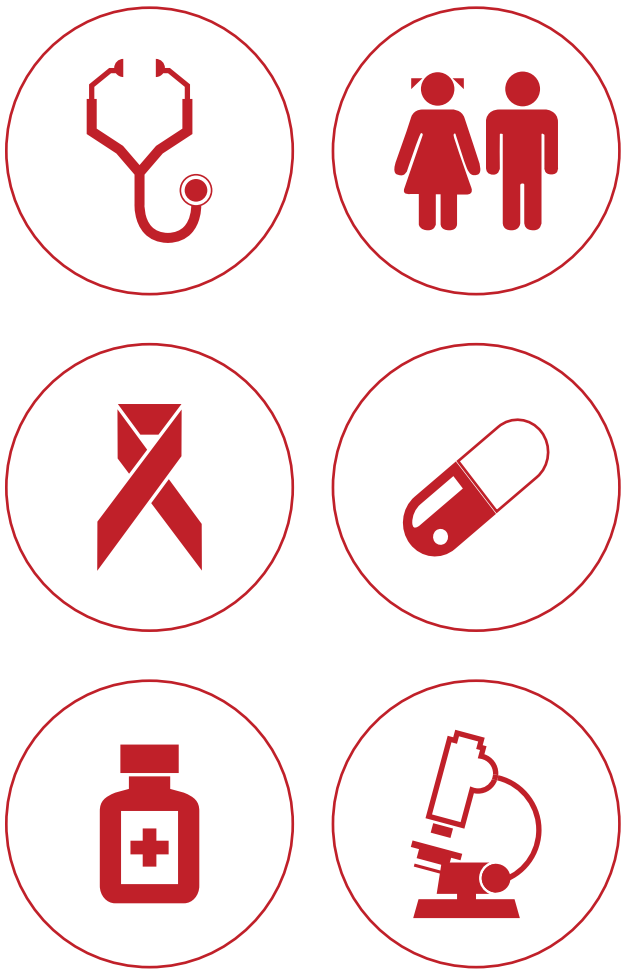
TECHNOLOGY LANDSCAPE

HIV RAPID DIAGNOSTIC TESTS FOR SELF-TESTING

December 2016
Semi-annual update



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Overview

The UNITAID HIV Rapid Diagnostic Tests for Self-Testing Landscape was first published on World Aids Day in December 2015, as part of an effort to build an understanding of the HIV self-testing (HIVST) market. A second edition was published in July 2016 at the International AIDS Conference, with a focus on description of new technologies and the products available or in the pipeline. Both documents are available from http://unitaid.org/en/resources/publications/technical-reports#hiv.

This document provides an update to the last edition[1]. Relevant updates are included for the following areas of the HIVST market and technology landscape:

- **HIVST enabling environment:** critical developments in policy and regulatory frameworks
- **HIVST demand:** market-size estimates for sub-Saharan Africa
- **HIVST supply:** updates on the technology pipeline

[1] The UNITAID HIV Rapid Diagnostic Tests for Self-Testing: Semi-Annual Update 2016 was compiled by Patrick Aylward (PSI), Petra Stankard (PSI), and Cheryl Johnson (WHO), in coordination with Olawale Ajose and Carmen Pérez-Casas (UNITAID). The material in the landscape was gathered by the authors from publicly available information, published and unpublished reports and articles and interviews with manufacturers and implementers. The market sizing work was adapted from a report published by PSI, "Expanding Access to HIV Self-Testing: A Market Development Approach".

Enabling Environment

Policy updates

On 29 November, 2016 the World Health Organization (WHO) released the first-ever recommendation on HIV self-testing, stating that: "**HIV self-testing should be offered as an additional approach to HIV testing services**[i]". This recommendation was based a synthesis of five randomized controlled trials, 25 studies on the performance and accuracy of HIV rapid diagnostic tests for self-testing, 125 studies on HIVST values and preferences and 4 studies on costs and cost-effectiveness. Overall WHO's review concluded that, when compared to standard facility-based HIV testing, HIVST:

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

The guidelines also recommend that programmes consider adapting, developing and harmonizing existing national policies on HIV testing to incorporate HIVST. Since the second edition of the UNITAID HIVST Landscape was published in July, policy at the country level has gained traction. As of October 2016, 23 countries now report the existence of a policy supportive of HIVST (up from sixteen), while another sixteen countries have policies that are under development[ii,iii]. Despite these shifts in policy, implementation of HIVST remains limited and is primarily implemented only in high-income settings or in the context of research.

TABLE 1

Countries with supportive or planned HIVST policies, as of October 2016[iv]

Supportive HIVST policies in place		Supportive HIVST policies under development	
Australia	Lesotho	**Belgium***	**Netherlands**
Belarus	Malawi	**Botswana**	**Nigeria**
Brazil	**Monaco**	**Central African Republic**	**Portugal**
Burundi	Rwanda	China	**Swaziland**
Democratic Republic of the Congo	South Africa	**Czech Republic**	**Zimbabwe***
Denmark	Spain	**Estonia**	
France	**Ukraine**	**Germany**	
India	United Kingdom	**Iran (Islamic Republic of)**	
Kenya	United Republic of Tanzania	**Latvia**	
Lao People's Democratic Republic	United States of America	**Mali**	
Lebanon	**Viet Nam**	**Namibia**	
	Zambia		

*Country that has adopted a supportive HIVST policy since October 2016.
Bold font indicates that policy status in the country has changed since July 2016 Landscape.
The HIVST policy environment is changing rapidly. The most up-to-date information about policy adoption is available at HIVST.org.

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Regulatory frameworks and quality assurance

As of November 2016, there are four HIVST rapid tests (one oral-fluid and three blood-based) approved for use by a founding member of the Global Harmonization Task-Force. While these products could be eligible for procurement by major donors, such as Global Fund or UNITAID, and by the President's Emergency Plan for AIDS Relief (PEPFAR) for those approved by FDA, they are for the most part targeting high-income markets and prices are currently a bottleneck for adoption elsewhere.

WHO Prequalification of In Vitro Diagnostics (IVDs) Programme is now actively accepting and reviewing HIVST manufacturer applications for prequalification. As of November 2016, two HIVST products are under review and if prequalified could become eligible for procurement by all major donors (Global Fund, PEPFAR, UNITAID). WHO plans to finalize the technical specification for HIVST products before the end of 2016: http://www.who.int/diagnostics_laboratory/evaluations/en/.

In addition, the UNITAID/Global Fund Expert Review Panel for Diagnostics (ERPD) has reviewed several dossiers and provided advice on one additional product that could be procured with Global Fund or UNITAID funds within time restrictions and upon specific conditions and request from programmes. Another ERPD call for HIVST is to be launched imminently and additional manufacturers are expected to submit product dossiers for review.

Demand

Potential adoption and market size

PSI, in partnership with Accenture Development Partners (ADP) and with the support of the Bill and Melinda Gates Foundation, analyzed the potential size of the HIVST market to highlight how the market may develop and illustrate the 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% of the global HIV burden. In 2015, these countries tested approximately 48 million adults for HIV[v].

Key findings from this analysis show that:

- With investments to modify currently unfavorable 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 analyzed.
- The most likely avenues for distribution include community-based testing channels and private sector pharmacies. Increasing the testing frequency of key populations may also be a promising way to grow the market.

TABLE 2

Market Size Estimates by Distribution Channel and Model Scenario (level of investment)

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

These market size estimates have some limitations. First of all, the self-testing market is nascent, with most products still in development. While HIV self-test use is growing in high-income markets, HIVST use in low- and middle-income countries (LMICs) is mostly restricted to research purposes and pilot programs, with some additional growth in private markets. This work in LMIC includes the largest HIVST program, STAR (a UNITAID-supported program in Malawi, Zambia and Zimbabwe implemented by a consortium led by PSI). The market is also subject to a number of constraints including high prices, and considerable uncertainty about the degree to which donors and governments will support the development of the HIVST market.

Moreover, the market sizing model focuses on identifying the total number of people with undiagnosed HIV that are required to meet the 90- 90-90 targets and did not consider markets resulting from other prevention activities such as pre-exposure prophylaxis and voluntary male medical circumcision. Finally, the publication of data on other distribution models (such as use of HIVST within provider-initiated testing and counseling) could substantially change the overall estimated market size. 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".

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Supply

Technology pipeline

Since the July landscape, only one new HIV self-test has been marketed—bioLytical's INSTI HIV Self-Test which was introduced in the United Kingdom and France in November 2016. In December, AAZ Labs' autotest VIH will also be introduced in Belgium, Czech Republic, Germany, the Netherlands, Poland, Portugal, and Spain. In addition, both bioLytical and BioSURE plan to market their HIVST products in private pharmacies in Kenya in early 2017.

The pipeline is large with eight fingerstick/whole blood-based and three oral fluid-based RDTs for self-testing under development. All products are serology tests. Nearly all use immunochromatographie (lateral flow) and one uses immunofiltration. The majority are second generation RDTs, with three third generation RDTs under development.

Available and pipeline products are summarized in Tables 3 and 4.

TABLE 3

Available HIV RDTs for self-testing with approval from regulatory authorities in founding-member countries of the Global Harmonization Task Force

Assay name (manufacturer)	Generation	Sensitivity	Specificity	Approval status	Approximate price per test (US$)
OraQuick® In-Home HIV Test (OraSure Technologies Inc., USA)	2nd generation	91.70%	98.70%	FDA	US$ 36-40 to consumers
autotest VIH® (AAZ Labs, France)	2nd generation	100.00%	99.80%	CE marked	US$ 25–28 to consumers
BioSURE HIV Self Test (BioSURE, United Kingdom)	2nd generation	99.70%	99.90%	CE marked	US$ 40–48 to consumers
	2nd generation	99.70%	99.90%	CE marked	US$ 7.50–15 to public sector
INSTI HIV Self Test (bioLytical Laboratories, Canada)	3rd generation	100.00%	99.80%	CE marked	US$ 36 to consumers

TABLE 4

Pipeline for HIV RDTs for self-testing

Assay name (manufacturer)	Specimen	Generation	Sensitivity	Specificity	Approval status	Approximate price per test (US$)
Atomo HIV Self-Test *(AtomoDiagnostics, Australia)*	Whole blood	3rd generation	NA	NA	No info	NA
Exacto® HIV Screening Test *(Biosynex Medtech, France)*	Whole blood	3rd generation	NA	NA	Submitting dossier for CE mark	NA
HemaDiagnostics Self-Test *(Hema Diagnostics Systems LLC, USA)*	Whole blood	NA	NA	NA	No info	Price available upon request
To be named *(Chembio Diagnostics Systems, USA)*	Whole blood	2nd generation	NA	NA	No info	NA
To be named *(Alere, USA)*	Whole blood	NA	NA	NA	No info	NA
To be named *(Trinity Biotech Ltd, Ireland)*	Whole blood	NA	NA	NA	No info	NA
To be named *(Premier Medical Corporation, India)*	Whole blood	NA	NA	NA	No info	NA
To be named *(bioLytical Laboratories, Canada)*	Whole blood	3rd generation	NA	NA	No info	NA
OraQuick® HIV Self-Test *(OraSure Technologies, Thailand)*	Oral fluid	2nd generation	NA	NA	No info	NA
To be named *(Sedia Biosciences, USA)*	Oral fluid	NA	NA	NA	No info	NA
AwareTM HIV-1/2 OMT Oral HIV Self Test *(Calypte Biomedical, USA)*	Oral fluid	2nd generation	NA	NA	No info	NA

Pricing

The cost of HIV RDTs for self-testing varies widely. Pricing varies based on product, distribution channel, packaging requested, volumes procured, country policies and regulation, and importation taxes and fees, among other factors.

Currently in high-income markets, the recommended consumer price ranges between US$ 25 and US$ 48. However, BioSURE has also made a public sector version of its product, with a different version of packaging, available at US$ 7.50–15 to the United Kingdom's National Health Service and nongovernmental organizations (NGOs). Products in the pipeline do not yet have final price points but are likely to be available at a significantly lower cost than products currently in the market.

In low- and middle-income settings and in the context of research, HIV RDTs for self-testing have been made available at approximately US$ 3-16 per test. Anecdotal reports from Kenya suggest pricing as low as US$ 1 per test for professional use tests sold as self-tests in private pharmacies[vi,vii], while self-tests reportedly available in South Africa, through pharmacies or online, retail for as much as US$ 10[viii]. In Namibia, HIV self- tests currently retail direct to consumers for US$ 4–12[ix]. At the high end of this price range, in both Namibia and South Africa, some products include multiple tests.

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