

Recommendations for the Rapid Expansion of HIV Self-Testing in Fast-Track Cities



FAST-TRACK
CITIES

IAfAC
INTERNATIONAL ASSOCIATION
OF PROVIDERS OF AIDS CARE

ASLM
AFRICAN SOCIETY FOR LABORATORY MEDICINE



Abbreviations and Acronyms	2
Introduction.....	3
Fast-Track Cities: Mobilizing Local Communities to End AIDS as a Public Health Threat	5
HIV Self-Testing: A Potentially Transformative Strategy towards Ending AIDS as a Public Health Threat.....	6
Methodology for Development of HIV Self-Testing Recommendations	10
HIV Self-Testing Recommendations for Fast-Track Cities	12
Summary Recommendations.....	12
Conclusion	22
References	23
APPENDICES	
Appendix 1: HIV Self-Tests on the Market	27
Appendix 2: Search Strategy for Recommendations.....	29
Appendix 3: Advisory Panel	30
Appendix 4: HIV Self-Testing Resources.....	35
Appendix 5: List of Priority Fast-Track Cities	36

Abbreviations and Acronyms

ART	antiretroviral therapy
ASLM	African Society for Laboratory Medicine
CDC	US Centers for Disease Control and Prevention
CE	Conformité Européene
ERP-D	(Global Fund's) Expert Review Panel for Diagnostics
FDA	US Food and Drug Administration
GHTF	Global Harmonization Task Force on Medical Devices
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
HIVST	HIV self-testing
IAPAC	International Association of Providers of AIDS Care
IDU	injecting drug user
Ig	immunoglobulin
MSM	men who have sex with men
PEPFAR	US President's Emergency Plan for AIDS Relief
PLHIV	people living with HIV
PrEP	pre-exposure prophylaxis
RDT	rapid diagnostics test
SDG	Sustainable Development Goal
SW	sex worker
TB	tuberculosis
TGA	Therapeutic Goods Administration (Australia)
UN-Habitat	United Nations Human Settlements Programme
UNAIDS	Joint United Nations Programme on HIV/AIDS
USAID	United States Agency for International Development
WHO	World Health Organization

The International Association of Providers in AIDS Care (IAPAC), joined by the African Society for Laboratory Medicine (ASLM) and other partners, as well as global HIV and health experts, have developed global recommendations to expedite the introduction, uptake, and scale-up of HIV self-testing (HIVST) as part of the [Fast-Track Cities](#) initiative.^a Tailored to the specific needs of cities, these recommendations have been shaped to support and facilitate rapid implementation of 2016 World Health Organization (WHO) guidelines recommending that HIVST be offered as an additional approach to traditional HIV testing services (1). These global recommendations are intended for local decision-makers, policy-makers at the national level whose actions affect the scope of action in cities, international donors and technical agencies, city-based clinicians (both in the private and public sectors), and civil society and other stakeholders in Fast-Track Cities.

Traditionally, cities have been heavily impacted by HIV/AIDS and, by necessity, served as *first responders* to the HIV epidemic. These recommendations recognize that, given current urbanization trends, cities will need to play a pivotal role in attaining the Joint United Nations Programme on HIV/AIDS (UNAIDS) 90–90–90 targets by 2020 (2)^b and contributing toward the Sustainable Development Goal (SDG) of ending AIDS as a public health threat by 2030 (SDG 3.3). Fully leveraging HIVST is critical to reaching the estimated 40% of people living with HIV (PLHIV) worldwide who do not know their status. Increasing knowledge of HIV status will help optimize the HIV care continuum by facilitating the use of the most potent preventive and therapeutic tool in the HIV armamentarium – antiretroviral therapy (ART).

After describing the purpose and history of the Fast-Track Cities initiative, this document outlines the process by which IAPAC, ASLM, and partners developed these recommendations for Fast-Track Cities (3). The document then describes the key recommendations and reasons why rapid scale-up of HIVST is so important for attaining the 90–90–90 targets. Each recommendation is supported by a brief rationale, including citations to scientific studies that buttress and inform the recommendation.

The translation of breakthroughs in HIV science to changes in national policies and service delivery can take more than a decade (4, 5). Avoiding such delays in

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Fully leveraging HIV self-testing is critical to reaching the estimated 40% of people living with HIV worldwide who do not know their status.

^a For more information about the Fast-Track Cities initiative, please see www.fast-trackcities.org. For a list of Fast-Track Cities as of January 15, 2017, please see [Appendix 5](#). This list is updated regularly at www.iapac.org/cities.

^b The 90–90–90 targets provides that by 2020: (a) 90% of all people living with HIV will know their HIV status; (b) 90% of all people with an HIV diagnosis will receive sustained antiretroviral therapy; and (c) 90% of all people receiving antiretroviral therapy will achieve viral suppression.

the introduction of HIVST is pivotal to hopes for reaching the 90-90-90 targets. As the subsequent discussion and recommendations indicate, a commitment to innovation, evidence-based action, and new ways of doing business will be needed to fully realize the potential of HIVST to support attainment of the 90-90-90 targets.

Access to early HIV diagnosis and treatment is essential to prevent illness, death, and transmission. The availability of a new and easy self-testing option that specifically responds to the documented preferences of many people at risk of HIV infection is part of the solution to ending AIDS as a major public health problem. It can substantially increase the proportion of PLHIV who know their HIV status (the first 90 of the 90-90-90 targets), sharply lower the rates of late HIV diagnosis, alleviate stigma and discrimination, bolster HIV prevention efforts, and contribute toward an increase in the proportion of PLHIV who achieve viral suppression.

FAST-TRACK CITIES

Mobilizing Local Communities to End AIDS as a Public Health Threat

Throughout most of the global AIDS response, national governments have been the focus of action – for policy development, programs, and resource mobilization. Although national action is essential to hopes for ending AIDS as a public health threat, cities are often important drivers of change, innovation, inclusion, and multisectoral action to combat threats to health and well-being (6). As more than half the world's population now lives in cities (7), decision-makers and stakeholders in urban areas have a central role to play in accelerating their local AIDS responses and thus influencing their national AIDS epidemics. In sub-Saharan Africa, an estimated 45% of all PLHIV reside in cities, while in several countries, 60% or more of PLHIV make their home in a single city (8).

With the aim of leveraging the potential of cities to drive national progress towards ending AIDS as a public health threat, local and global leaders joined forces on World AIDS Day 2014 to launch the [Fast-Track Cities](#) initiative (3). At an event hosted by the Mayor of Paris, Ms. Anne Hidalgo, city leaders from around the world pledged to fast-track their local AIDS responses to attain the 90–90–90 targets by 2020 in their cities. By signing the *Paris Declaration on Fast-Track Cities Ending AIDS* (9), cities are highlighting the vital role they play in reducing new HIV infections, preventing AIDS-related deaths, while eliminating stigma as a barrier to accessing and utilizing HIV services.

High HIV burden cities from every region of the world have formally joined the Fast-Track Cities initiative as of January 15, 2017 (www.iapac.org/cities; see [Appendix 5](#)) (3). The initiative is supported by four core partners – the City of Paris, IAPAC, UNAIDS, and the United Nations Human Settlements Programme (UN-Habitat). Benefits to Fast-Track Cities include participating in a global network of like-minded cities using the initiative as a framework to guide and measure their progress, access technical support to increase the capacity of their local health departments, access web-based resources, report their progress via city-specific dashboards, utilize data to focus capacity-building and stigma elimination activities, and obtain assistance in mobilizing resources.

The Fast-Track Cities initiative is also an important vehicle to promote accountability in the AIDS response, as cities are encouraged to provide transparent annual reporting on progress utilizing harmonized metrics (3). Baseline data collected through the Fast-Track Cities' web-based monitoring and evaluation platform indicate that numerous cities have already made striking progress towards the 90–90–90 targets, offering hope that cities can achieve all or some of the target by the 2020 deadline (6).

By signing the *Paris Declaration on Fast-Track Cities Ending AIDS*, cities are highlighting the vital role they play in reducing new HIV infections, preventing AIDS-related deaths, while eliminating stigma as a barrier to accessing and utilizing HIV services.

HIV SELF-TESTING

A Potentially Transformative Strategy towards Ending AIDS as a Public Health Threat

A major gap in the HIV care continuum occurs at the very beginning, with the diagnosis of HIV infection, which serves as the gateway to HIV treatment for those who test positive.

Not only does a late HIV diagnosis increase the risk of illness, disability and death, but evidence also suggests that undiagnosed HIV infection contributes disproportionately to the number of new HIV infections.

In SDG 3.3, the world embraced the goal of ending AIDS as a public health threat by 2030. If the world hopes to reach this goal, achievement of the 90–90–90 targets is essential (10). Moving immediately to attain these targets by 2020 is pivotal, as a slower pace of scale-up may allow the HIV epidemic to rebound and prevent the world from seizing this historic opportunity to end the most serious pandemic of our time (10). Recognition of the urgent need to increase both HIV treatment uptake and rates of viral suppression is one of the primary reasons why local leaders across the globe have joined the Fast-Track Cities initiative.

A major gap in the HIV care continuum occurs at the very beginning, with the diagnosis of HIV infection, which serves as the gateway to HIV treatment for those who test positive. In 2015, an estimated 40% of PLHIV worldwide were unaware of their HIV status (11). Not only does a late HIV diagnosis increase the risk of illness, disability and death (12, 13), but evidence also suggests that undiagnosed HIV infection contributes disproportionately to the number of new HIV infections (14). The *IAPAC Guidelines for Optimizing the HIV Care Continuum for Adults and Adolescents*, released in 2015, specifically prioritize actions to increase knowledge of HIV status and commence earlier treatment (15). HIV testing also serves as the portal for a variety of HIV prevention services, including voluntary medical male circumcision, condoms, pre-exposure prophylaxis (PrEP) with antiretrovirals, partner notification, and couples counseling and testing. HIV testing can also prevent HIV-associated tuberculosis (TB) through earlier HIV treatment, isoniazid preventive therapy, and expedited evaluation for active disease if TB symptoms develop.

For purposes of these recommendations, HIVST is defined as a process whereby a person who wants to know his or her HIV status collects a specimen, performs a self-test, and interprets the test result in private. By providing an opportunity for people to test themselves discreetly and conveniently, optimally implemented HIVST programs provide people who are not currently reached by existing testing services with information about their HIV status and opportunities to link to and access HIV treatment and prevention services. HIVST has been used for years – both formally and informally – by healthcare workers and others in a wide variety of settings. In 2012, the US Food and Drug Administration (FDA) approved the first rapid HIV testing technology that detects the presence of HIV-1 and HIV-2 antibodies from oral fluid samples (16). Since 2012, rapid HIV tests have received Conformité Européenne (CE) marking and approval for use as home tests in Europe (17). Rapid test technology has swiftly advanced to improve the end-user experience, including the development of one HIV self-test that detects immunoglobulin (Ig)M and IgG, and that can be read immediately, while others have shortened the time for obtaining test results to around 15–20 minutes. Additional improvements include fewer steps, easier readability, and tests that use 2.5 µL finger-prick samples (see [Table A1](#) in [Appendix 1](#) for the characteristics of HIV self-tests currently available on the market). According to UNITAID, as of December 2016, 22 countries (18), representing approximately 50% of estimated global HIV burden (19), have policies supporting HIVST, and their cost in low- and

middle-income countries continues a downward trend (see [Box 1](#) for information about the cost of HIV self-tests). Additional reliable tests are in the pipeline and an increasing number of countries have a supportive policy; the focus is now on accelerating access to this potentially life-saving technology for PLHIV.

Rapid testing technology has swiftly advanced, with four products receiving regulatory approval as of December 2016 (see [Table 1](#) for detailed information on each of the approved tests). Further developments and additional technologies are anticipated.

Table 1. Available HIV Rapid Diagnostic Tests for Self-Testing with Approval from Regulatory Authorities

Assay name (manufacturer)	Type	Sample	Sensitivity (%)	Specificity (%)	Approval status (self-test)	Approximate price per test (US\$)*
Autotest VIH® (AAZ Labs, France)	IgG antibody test	Fingerstick	100.00	99.80	CE marked	\$25–28 to consumers; \$8–15 for NGOs and distributors
BioSURE HIV Self Test (BioSURE, United Kingdom)	IgG antibody test	Fingerstick	99.70	99.90	CE marked	Price to UK retail consumers is US\$36 (includes 20% VAT) Price for supply to public sector is US\$7.50-12.00
INSTI HIV Self Test (bioLytical Laboratories, Canada)	IgM and IgG test	Fingerstick	100.00	99.80	CE marked	\$36 to consumers; for NGOs and distributors, cost depends on order size (e.g. \$3/test on offer for bulk sales in Africa)
OraQuick® In-Home HIV Test (OraSure Technologies Inc., USA)	IgG antibody test	Oral fluid	91.70	98.70	FDA	\$36–40 to consumers; no pricing outside USA for NGOs and distributors

CE: Conformité Européene; FDA: U.S. Food and Drug Administration

Source: The above table was adapted from UNITAID's resource document Technology landscape: HIV rapid diagnostic tests for self-testing. December 2016, Semi-annual update (http://unitaid.org/images/marketdynamics/publications/HIV_rapid_diagnostic_tests_for_self-testing_-_semi-annual_update-december_2016.pdf, accessed 30 December 2016). We advise those interested in up-to-date information to contact the manufacturers directly.

For more detailed information on the tests, *please see:* Autotest: <http://www.autotest-sante.com/en/autotest-VIH-par-AAZ-139.html>; BioSURE: <http://hivselftest.co.uk/>; INSTI self test: <https://www.insti-hivselftest.com/>; Oraquick in-home HIV test: <http://www.oraquick.com/FAQs>

*Pricing varies according to a number of factors including volume and setting; prices in Table are illustrative and may not reflect current rates; contact the manufacturer for more accurate quotes.

By enabling people to test themselves for HIV in private, HIVST offers an additional testing option for people who are not always reached by current testing approaches, including those who are deterred from accessing facility-based testing due to stigma. Studies in diverse populations in both high-income and resource-limited settings have found self-testing to be highly acceptable and often preferred to facility-based testing (20–32). Convenience, privacy, and the ability to obtain fast results are among the factors cited most often as benefits of HIVST among participants in acceptability studies (20,33,34). Studies have shown that the addition of HIVST increases testing uptake compared to facility-based testing alone. Based on this, it is projected that HIVST, by offering a self-directed and fully private testing option, will increase the frequency of HIV testing and early diagnosis among groups who are not currently well served by mainstream, facility- or community-based testing services (35). These groups include men (34,36), key populations (20,26,31,37), and residents of informal settlements where health facilities may be scarce (32). HIVST could also help accelerate the uptake of PrEP, a primary prevention intervention that relies on frequent HIV testing of HIV-uninfected people who are at risk for HIV infection. Further implementation research is needed to define the optimal role of HIVST in PrEP delivery. Where HIVST is performed with the assistance of a healthcare provider, it represents an additional advance toward a task-shifting or task-sharing model for HIV services, whereby certain tasks traditionally performed by higher-level health cadres are transitioned to lower-level workers or to the community (38).

In December 2016, WHO formally recommended HIVST as an additional approach to HIV testing services (1). Under the WHO guidelines, people who have a reactive (positive) self-test result should receive further testing to confirm their diagnosis, using the relevant validated national HIV testing algorithm. WHO recommends that persons who experience difficulty in self-testing or who are uncertain about their self-test result should seek assistance through facility- or community-based HIV testing services. Persons who have a non-reactive negative self-test do not usually require further HIV testing, although individuals accessing HIVST need to be informed about the window period. (For further information on the window period, see Box 2.) In addition to offering treatment to prevent illness, death and transmission, WHO also recommends that programs consider offering assisted partner notification for people diagnosed with HIV as part of HIV services.^c

^c The new WHO guidelines also address partner notification (<http://www.who.int/hiv/pub/vct/hiv-self-testing-guidelines/en/>).

Box 1. Making HIV Self-Tests Affordable

Manufacturers are working to make HIV self-tests available to developing world settings at lower costs. 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, while self-tests reportedly available in South Africa, through pharmacies or online, retail for as much as US\$ 10. In Namibia, HIV self-tests currently retail direct to consumers for US\$ 4–12. At the high end of this price range, in both Namibia and South Africa, some products include multiple tests.

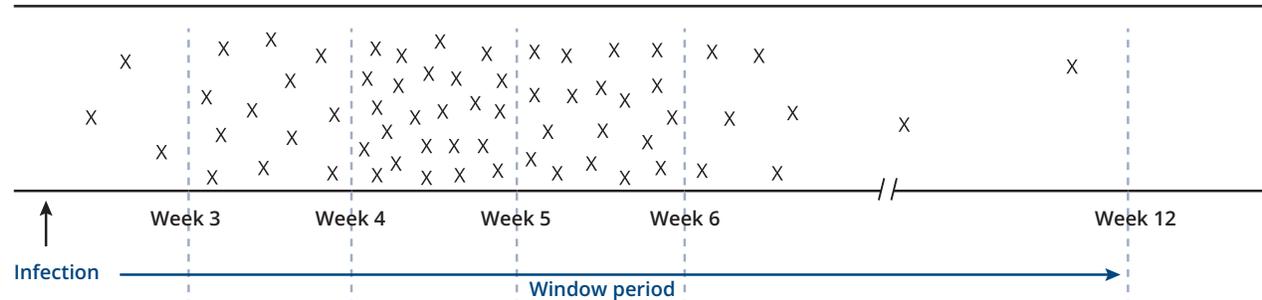
Source: BGMF, PSI, WHO, UNITAID. Technology landscape: HIV rapid diagnostic tests for self-testing. Geneva: UNITAID; December 2016 (http://unitaid.org/images/marketdynamics/publications/HIV_rapid_diagnostic_tests_for_self-testing_-_semi-annual_update-december_2016.pdf, accessed 16 December 2016).

Box 2. Window Period and HIV Self-Testing

The *window period* is a source of some confusion for providers and individuals alike. No HIV test can detect HIV immediately after infection—it takes time for the virus to replicate and for the body to develop antibodies to the virus. The time between a potential exposure to HIV infection and the time when an HIV test will give an accurate result is known as the window period of detection. This is the time taken by the body to produce antibodies in sufficient quantity to be detectable. The window period varies from person to person and also depends on the type of HIV test, as some tests detect antibodies earlier than others. Depending on the tests and the individual, this can be from around 21 days to around three months when most people (99%) will be antibody positive after they are infected.^{1,2} In other words, a negative result may not be accurate until three months after infection. During the window period, a person can be infected with HIV and be very infectious but still test HIV negative as they have not yet produced detectable antibodies to HIV.

While the window period is important for definitively excluding infection, it does not mean that people should wait 3 months to take a test, as the HIV self-tests can detect infection in some people within a matter of weeks. People need to consider their individual risks for HIV exposure and how often they would like to test themselves to catch recent infection earlier and/or confidently exclude HIV infection (i.e., no exposure within three months of an HIV negative test).

UNDERSTANDING THE WINDOW PERIOD



Each “x” represents the time when a different person develops antibodies. Some people develop antibodies rapidly and for others it may take up to three months. Early testing can help pick up HIV infection after a few weeks but the only way to be sure one is not infected is to do a test at three months after exposure.

Adapted from: <http://i-base.info/guides/testing/what-is-the-window-period>

References

- ¹ Delaney KP, Hanson DL, Masciotra S, Ethridge SF, Wesolowski L, Owen SM. Time until emergence of HIV test reactivity following infection with HIV-1: Implications for interpreting test results and retesting after exposure. *Clin Infect Dis*. 2016. doi: 10.1093/cid/ciw666. Advance access published online November 3, 2016.
- ² Online Supplementary materials for Delaney KP, Hanson DL, Masciotra S, Ethridge SF, Wesolowski L, Owen SM. Time until emergence of HIV test reactivity following infection with HIV-1: Implications for interpreting test results and retesting after exposure. *Clin Infect Dis*. 2016. doi: 10.1093/cid/ciw666. Advance access published online November 3, 2016.

Additional Resources

- <https://www.cdc.gov/actagainstaids/basics/testing.html>
<http://www.who.int/mediacentre/factsheets/fs360/en/>
<http://apps.who.int/iris/bitstream/10665/251655/1/9789241549868-eng.pdf>

Methodology for Development of HIV Self-Testing Recommendations

By convening a process to develop these recommendations, IAPAC and ASLM aimed to facilitate identification and use of evidence-based approaches to support full implementation of the 2016 WHO guidelines on HIVST. As these recommendations are not intended to serve as formal guidelines but rather to assist [Fast-Track Cities](#) in taking immediate action to fully leverage opportunities presented by HIVST, IAPAC and ASLM implemented a streamlined consultative process that drew on the expertise of an international, multidisciplinary advisory panel. The Advisory Panel was co-chaired by Drs. Alash'le Abimiku (ASLM), John Nkengasong (US Centers for Disease Control and Prevention [CDC]), and Reuben Granich (IAPAC). The co-chairs helped steer the process and served as the link with the writing team, which included a data analyst and a technical writer. The Advisory Panel included over 40 experts from Africa, Asia, Europe, Latin America, and North America (see [Appendix 3](#) for the full list). All Advisory Panel members submitted Conflict of Interest forms, which were reviewed for potential conflicts before their comments were incorporated.

To support the Advisory Panel in developing the recommendations, IAPAC commissioned an extensive search and review of the published scientific literature on HIVST. Experts from the CDC's Prevention Research Synthesis (PRS) Project conducted the search (see [Appendix 2](#) for full searches as implemented in each database). Articles that captured the area of interest provided by the co-chairs were used to help develop and assess the search. Librarians with extensive experience in the subject of HIV prevention conducted systematic searches of four electronic databases (MEDLINE, EMBASE, CINAHL, and PubMed) by cross-referencing multiple search terms (i.e. keywords and each database's index terms) in two areas: (i) HIV descriptors (*HIV seropositivity, HIV infections, various keywords for HIV*), and (ii) self, home or rapid testing (*diagnostic self-evaluation, diagnostic kit, various keywords for testing*). On October 12, 2016, a search for citations published between 2000 and 2016 was performed in the databases as outlined here:

1. CINAHL (Cumulative Index to Nursing and Allied Health Literature) was searched on the EBSCOhost platform – 907 citations were retrieved.
2. EMBASE (Excerpta Medica Database) was searched on the OVID platform – 2658 citations were retrieved.
3. MEDLINE (Medical Literature Analysis and Retrieval System Online) was searched on the OVID platform – 2329 citations were retrieved.
4. PubMed (from the National Library of Medicine) was searched via the Internet – 221 citations were retrieved.

Using some of the references as a starting point, the technical writing team conducted a secondary search and retrieved additional references. After

duplicates were removed, 5542 citations were available for review in Endnote reference manager. Using the scientific literature and policy context, the recommendations were drafted by the co-chairs and technical writing team, and reviewed by the Advisory Panel. The technical writer and a co-chair reviewed the citations generated by the search to assess their relevance to the recommendations on implementation of HIVST, uptake, and scale-up in Fast-Track Cities. The recommendations and supporting science were then further reviewed by the co-chairs, technical writer and Advisory Panel, and prepared by the scientific writing team for publication.

HIV Self-Testing Recommendations for Fast-Track Cities

To fully implement the new WHO guidelines on HIVST and maximize the public health impact of HIVST, [Fast-Track Cities](#) are recommended to take several key actions (see Box 3 on [Summary Recommendations](#)). These include specific steps that cities themselves can take, as well as advocacy targeting key decision-makers, especially national regulatory and health authorities in cases where cities lack the power on their own to ensure the availability, affordability, uptake, and impact of HIVST in cities.

Box 3. Summary Recommendations

1. Fast-Track Cities and their stakeholders should support and facilitate access to HIV self-tests for use at home and/or in assisted HIVST settings.
2. Fast-Track Cities should work with HIV programs and donors to support the widespread availability of quality-assured, affordable HIV self-tests for everyone, with a focus on vulnerable populations.
3. Fast-Track Cities should encourage actions by appropriate stakeholders to make the price of HIV self-test kits as low as possible, through such potential strategies as price reductions, market diversification, pooled procurement, price transparency, market forecasting and subsidized pricing or for free. Full costing of HIV self-test commodities and programs should be included in national budgets or requests for donor support.
4. Fast-Track Cities should support and monitor efforts to expand access to HIVST as part of achieving the first 90 as the key initial step to achieving the 90–90–90 targets.
5. Fast-Track Cities should focus efforts on accelerating regulatory and supply chain processes to facilitate rapid uptake of HIVST by identifying and addressing obstacles.
6. Fast-Track Cities should support surveillance, and other monitoring and evaluation measures to assess individual barriers to HIVST.
7. Fast-Track Cities and stakeholders, providers and community-based organizations should develop communication and educational programs, and marketing campaigns that are designed to encourage HIVST.
8. Fast-Track Cities and stakeholders should optimize service delivery to welcome into clinical services people who self-refer after HIVST.
9. Fast-Track Cities should remove technical and administrative barriers to improve access to HIVST.

1. Fast-Track Cities and their stakeholders should support and facilitate access to HIV self-tests for use at home and/or in assisted HIVST settings.

Fast-Track Cities and their stakeholders should support, facilitate and/or advocate with relevant national authorities for access to HIVST^d (i.e., private home-based testing, private testing in other venues without assistance) and, where resources permit, assisted HIVST (e.g., testing with the help of a healthcare provider in clinics and hospitals, and community-based testing efforts). While assisted HIV testing has an important role to play in diagnosing HIV, efforts to promote access to testing for people at risk of HIV should include a strong emphasis on fully private, unassisted HIVST. Fast-Track Cities should formalize their support for HIVST, either as part of an updated HIV policy or strategy, or as a stand-alone policy circular. If local public health law permits, ordinances to support HIVST, conducted using high-quality tests, could be considered on an emergency basis.

While assisted HIV testing has an important role to play in diagnosing HIV, efforts to promote access to testing for people at risk of HIV should include a strong emphasis on fully private, unassisted HIVST.

Rationale

Research studies and pilot projects have validated multiple models for HIVST, including wholly unassisted HIVST as well as various forms of assisted HIVST (39–41). These include individual use at home or in other private settings, without assistance by a healthcare provider, or in service settings (e.g. clinic and/or outreach setting), with some form of assistance provided by a healthcare provider (e.g. nurse, doctor, lay or peer counselor, research study staff).

According to a systematic review of the available evidence, specificity is high for both assisted and unassisted models of HIVST (42). Although the sensitivity of unassisted HIVST has been found to be slightly lower than that of assisted HIVST (42), the benefits of unassisted HIVST in increasing HIV screening and early entry to care clearly outweigh the small risks of a false test result. Confirmatory testing is still needed for individuals who have a reactive (positive) self-test result, and people taking the test will need to understand the meaning of a negative test.

Ensuring access to HIVST would honor individual autonomy and respond to the clear preferences of at-risk communities for testing options that are optimally private and confidential (34). Given the evidence regarding the diversity of needs and preferences with respect to testing technologies and service approaches among people at risk of HIV infection (43,44), making both unassisted and assisted HIVST

^d For the purposes of this document, HIVST is by definition private and fully self-administered. HIVST includes the individual's performing the test and interpreting the results. Assisted HIVST includes assistance from a trained healthcare worker or volunteer to assist with performing and/or reading the test.

available will enhance individual autonomy by enabling the user to determine the approach that best fits individual needs and circumstances, and will also help to fully leverage the potential of HIVST technologies to accelerate progress toward the first 90 of the 90–90–90 targets.

2. Fast-Track Cities should work with HIV programs and donors to support the widespread availability of quality-assured, affordable HIV self-tests for everyone, with a focus on vulnerable populations.

Rationale

Studies have found HIVST to be highly accurate (41,42) and robust to the environment (45). However, for HIVST, as for any other novel technology, mechanisms and systems for quality assurance should be in place (21,46). There are a number of regulatory authorities that review and ensure diagnostic test quality, including but not limited to FDA, CE Mark (European Conformity) (17) and the WHO prequalification program. For example, WHO's prequalification procedures aim to ensure that all HIV self-tests that are available for use are of acceptable quality. (For information on WHO requirements for prequalification of HIVST technologies, see <http://apps.who.int/iris/bitstream/10665/251857/1/9789241511742-eng.pdf?ua=1>.)

Affordability is addressed in **Recommendation 3** and should be considered in the context of vulnerable populations, including but not limited to the poor, key populations (men who have sex with men [MSM], sex workers [SW], people who inject drugs [PWID]), young women and others at increased risk of HIV infection.

3. Fast-Track Cities should encourage actions by appropriate stakeholders to make the price of HIV self-test kits as low as possible, through such potential strategies as price reductions, market diversification, pooled procurement, price transparency, market forecasting, and subsidized pricing or for free. Full costing of HIV self-test commodities and programs should be included in national budgets or requests for donor support.

Rationale

In settings where individuals purchase HIV self-test kits on their own, pilot studies and environmental assessments have found that the cost associated with HIVST may pose an impediment to utilization for some individuals and populations (28,47,48). Efforts are needed to minimize the costs of HIV self-test kits, and to provide access to free or subsidized HIVST for those who are unable to afford it on their own.

Cost is also an important consideration for procurement by national programs and international donors, who must fit new technological options within finite budgets. Minimizing the costs of procuring HIV self-test kits will help enhance the considerable cost-effectiveness of HIVST (49). While traditional costing efforts focus on the price point and the resources necessary to procure HIV tests, Fast-Track Cities should consider more sophisticated costing analyses and outcomes that take into account the potential cost-savings of early diagnosis in preventing illness, death and transmission.

Although HIV self-test kits are not especially costly (50), achieving the lowest possible cost will enable and accelerate scale-up. Proactive steps are warranted to shape the market in such a way as to incentivize cost reductions. Market-shaping entities – such as UNITAID (<http://www.unitaid.eu/en/>) and the Clinton Health Access Initiative (<http://www.clintonhealthaccess.org>) – and buyers with the power to influence the market – such as the US President's Emergency Plan for AIDS Relief (PEPFAR, <http://www.pepfar.gov/>); the Global Fund to Fight AIDS, Tuberculosis and Malaria (<http://www.theglobalfund.org/en/>); and governments, including South Africa (51),^e India, Brazil, China and Russia, should collaborate to develop innovative means to drive prices lower. Another example of negotiated price reductions is the lowering of prices for viral load test kits by Roche through its Global Access Program (52). Other examples of such measures are emergency waivers or fast-tracked approvals by national regulatory bodies, pooled procurement, price transparency for quality-assured commodities, and market intelligence such as reliable quantification and long-term forecasting, open tendering, upfront bulk purchases, volume guarantees and other incentives.

4. Fast-Track Cities should support and monitor efforts to expand access to HIVST as part of achieving the first 90 as the key initial step to attaining the 90-90-90 targets.

Fast-Track Cities should support and monitor efforts to expand access to HIVST as part of attaining the first 90 of the 90–90–90 targets (and, subsequently, the 95–95–95 targets by 2030). Fast-Track Cities should work with the private sector, HIV care providers and communities to provide national and local leadership to facilitate access to HIVST and linkage to care as part of efforts to attain the 90–90–90 targets. People living in Fast-Track Cities should advocate for access to HIVST and treatment for their partners, family members, and communities. Every effort should be made to support and, when necessary,

While traditional costing efforts focus on the price point and the resources necessary to procure HIV tests, Fast-Track Cities should consider more sophisticated costing analyses and outcomes that take into account the potential cost-savings of early diagnosis in preventing illness, death and transmission.

^e For information on the ability of South Africa's HIV-related tender offers to influence prices globally, see reference (51): Clinton Health Access Initiative. ARV Market Report: The state of the antiretroviral drug market in low- and middle-income countries, 2014–2019. November 2015 (http://www.clintonhealthaccess.org/content/uploads/2015/11/CHAI-ARV-Market-Report-2015_FINAL.pdf).

Fast-Track Cities should work with the private sector, HIV care providers and communities to provide national and local leadership to facilitate access to HIVST and linkage to care as part of efforts to attain the 90–90–90 targets.

Innovative approaches – such as a 24-hour helpline and a dedicated website – should be explored to facilitate confirmatory testing and linkage to care for individuals who have used HIVST.

provide leadership for other government agencies charged with promoting and/or regulating access to HIVST. Monitoring and making public progress in accelerating access to HIVST is critical for identifying successes and addressing challenges.

Rationale

HIVST has the potential to accelerate efforts to close the gap between current knowledge of HIV status (60% of all people living with HIV (11)) and the first 90 of the 90–90–90 targets. While current access to HIVST in low- and middle-income countries can be measured in the thousands, UNITAID and WHO project that global demand for HIVST could range from 4.8 million to as high as 88.2 million in 2018 (50). In nine high-burden countries in Africa (Kenya, Malawi, Mozambique, Nigeria, South Africa, Tanzania, Uganda, Zambia and Zimbabwe), UNITAID projects that the market could reach 3.3–5.7 million HIVST kits per year if donors and countries support HIVST scale-up (53). Recognizing the need to achieve swift uptake of HIVST in order to speed progress toward achievement of the first 90, political and community leadership is urgently needed in Fast-Track Cities to raise awareness of HIVST, educate individuals at risk on ways to obtain HIVST, and promote uptake of HIVST to increase knowledge of HIV status. Support should be given to community-based organizations to improve HIVST literacy and accelerate HIVST demand and uptake.

The promise that HIVST will improve health outcomes for PLHIV will be realized only if people who have a reactive self-test result obtain confirmatory testing and treatment services in a timely manner. Available evidence indicates that people who test HIV-positive with HIVST generally seek confirmatory HIV testing and enroll in HIV care and treatment services (20,44). However, Fast-Track Cities should take proactive measures to maximize swift linkage to care for people who use HIVST by educating users on the importance of follow-up care and on the sources of confirmatory testing, and HIV care and treatment services. Innovative approaches – such as a 24-hour helpline and a dedicated website – should be explored to facilitate confirmatory testing and linkage to care for individuals who have used HIVST. As HIVST is rolled out, best practices for linkage to care should be documented and widely disseminated.

With the support of international donors and technical agencies, countries are already taking steps to design monitoring and evaluation systems in a manner that will ensure collection and use of data regarding outcomes across the HIV treatment cascade. As part of tracking the first 90 target, national monitoring and evaluation systems should incorporate specific mechanisms to monitor the contribution of HIVST in closing HIV testing gaps. In particular, existing data collection tools will need to be adapted to capture the results of confirmatory testing of individuals who previously had a reactive self-test result.

5. Fast-Track Cities should focus efforts on accelerating regulatory and supply chain processes to facilitate rapid uptake of HIVST, by identifying and addressing obstacles.

Where necessary, Fast-Track Cities should support local and national HIV programs to urgently issue regulations that allow the sale and distribution of good-quality tests in the private sector. If allowable under public health law, local ordinances may be issued to allow high-quality HIVST on an emergency basis. Fast-Track Cities should support their national Ministry of Health, in collaboration with other key ministries, to expedite regulatory processes for HIVST, including acceptance of a comprehensive review and approval of HIVST technologies by an external recognized agency (e.g., FDA, CE Mark, WHO prequalification, etc.). Fast-Track Cities and their stakeholders should also advocate to ensure that national and international agencies (e.g., FDA, CE Mark, WHO prequalification) share their dossiers of HIVST products with other regulatory agencies to facilitate the appeal for waivers of a full regulatory review and hence expedite approval.

Rationale

In many countries, national regulatory bodies are not sufficiently resourced to ensure the rapid review and approval of new diagnostic technologies (54). As a result, needless delays are common with respect to the introduction of breakthrough medical technologies, such as new diagnostic tools for priority diseases. However, there are also examples, such as rapid diagnostic tests, where urgent, focused attention has resulted in swift regulatory approval of new diagnostic tools (53). Recent efforts to harmonize regulatory requirements for new medical technologies have improved regulatory processes in many countries, but years-long delays in the availability of priority medicines and diagnostics are still frequent.

Given the urgency of achieving the first 90 of the 90–90–90 targets, expediting regulatory processes to facilitate the earliest possible roll-out and uptake of HIVST is an immediate global health priority. HIVST diagnostic technologies have been rigorously scrutinized by the FDA and the European Medicines Agency (WHO prequalification is pending). Ensuring that new products are of acceptable quality and that their benefits outweigh their risks is of paramount importance, but steps are also needed to avoid unnecessary delays associated with a country-by-country review of HIVST technologies that have already been exhaustively evaluated by leading regulatory agencies. Fast-Track Cities should encourage their national governments to examine emergency waiver options while also looking to WHO and stringent regulatory authorities for guidance on HIVST. Where a version of a self-test product has already been approved for professional use, approval of the product for home use should be expedited. Countries may also consider HIVST products that are approved by the Global Fund's Expert Review Panel for Diagnostics (ERP-D)

Ensuring that new products are of acceptable quality and that their benefits outweigh their risks is of paramount importance, but steps are also needed to avoid unnecessary delays associated with a country-by-country review of HIVST technologies that have already been exhaustively evaluated by leading regulatory agencies.

Fast-Track Cities should encourage national decision-makers to avoid placing unnecessary restrictions on the channels through which HIVST technologies may be sold or distributed. In particular, pharmacies should be permitted to provide HIV self-test kits without medical prescription or supervision.

system. The dossiers for the various regulatory and approval processes represent considerable time and effort. Mechanisms to standardize and share information across regulatory agencies should be encouraged to reduce costs for manufacturers and bureaucracies, expedite approvals, and facilitate requests to waive parallel approval requirements. While quality is important, redundancy and bureaucracy is not and every effort should be made to speed access to this technology for people living with HIV.

Fast-Track Cities should also encourage national decision-makers to avoid placing unnecessary restrictions on the channels through which HIVST technologies may be sold or distributed. In particular, pharmacies should be permitted to provide HIV self-test kits without medical prescription or supervision, as studies in diverse settings indicate that many individuals, including members of key populations, often prefer over-the-counter access (20,55–58). Likewise, stipulations to ensure linkage to care, provide assisted HIVST, or support partner notification should be avoided to reduce barriers to access to HIVST by people at risk for HIV. To make over-the-counter access feasible, Fast-Track Cities and their national decision-making partners may need to consider price subsidies or other broader market interventions to ensure financial incentives for pharmacies to participate in the roll-out of HIVST.

6. Fast-Track Cities should support surveillance, and other monitoring and evaluation measures to assess individual barriers to HIVST.

Fast-Track Cities should support surveillance, and other monitoring and evaluation activities to assess individual and systemic barriers to HIVST, including but not limited to purchase cost, stigma, social harms, understanding about test quality, proximity of sale outlet to the individual, and ease and simplicity of the pathway following a positive or negative test. Systems should be in place to monitor adverse events such as human rights violations associated with HIVST. These could include coercive testing and improper use of HIVST (e.g., for employment, etc.).

Rationale

Surveillance and other monitoring and evaluation measures to assess individual barriers to HIVST should be part of routine monitoring and evaluation of progress toward attaining the 90–90–90 targets. Studies have found little reason to believe that HIVST will result in extreme adverse events, such as social harms or severe emotional distress (39,42,59,60). However, as HIVST is rolled out, systems should be in place to monitor adverse events related to the use of HIVST (21). Fast-Track Cities should enforce and maintain a blanket prohibition against the coercive or otherwise non-consensual use of HIVST.

7. Fast-Track Cities and stakeholders, providers and community-based organizations should develop communication and educational programs, and marketing campaigns that are designed to encourage HIVST.

The greatest risk to the accuracy of HIVST results appears to be associated with inappropriate use of the product, including as a result of the user's inability to understand product instructions (22,23,61,62). Communication, education and marketing programs should encourage HIVST and explain the procedure. As appropriate, these programs should include basic information regarding HIVST (e.g., where to procure the tests, the meaning of positive and negative test results, acute and early infection, the importance of linkage to care), demonstrations of the self-testing procedure (e.g., user training/ materials), information regarding how the self-testing kits are distributed and how linkages to care and services are made (operationalized) after self-testing. Including through advocacy with appropriate national authorities, Fast-Track Cities should ensure that HIV self-test kits include clear, easy-to-use instructions in a packet insert that can be accessed and interpreted by users with low literacy (21). Attention is also needed to ensure that written instructions that accompany HIV self-test kits are culturally appropriate for those who need them. Adaptation and revision of written instructions should be ongoing, taking into account lessons learned as a result of HIVST roll-out. Although some of these topics may already be addressed by existing communication and education efforts, the novelty of HIVST will inevitably create questions that require HIVST-specific materials and strategies.

Fast-Track Cities should ensure that HIV self-test kits include clear, easy-to-use instructions in a packet insert that can be accessed and interpreted by users with low literacy. Attention is also needed to ensure that written instructions that accompany HIV self-test kits are culturally appropriate for those who need them.

Rationale

New diagnostic, prevention and treatment tools, even those that have the potential to dramatically improve health outcomes, do not achieve sufficient scale merely as a result of their introduction. For example, in the case of voluntary medical male circumcision, a highly cost-effective HIV intervention, disappointing early uptake led programs to identify behavioral and community mobilization, and demand creation strategies to encourage men to seek, and women to support their partners and sons in seeking, circumcision services (63).

As HIVST represents a notable departure from previous information and guidance on HIV testing services, educational programs will be needed to inform individuals and communities regarding HIVST and to encourage them to use it. Specifically, the importance of early diagnosis and immediate treatment irrespective of CD4 cell count to prevent illness, death and transmission is a new message that may be unfamiliar to healthcare providers and the community. Diverse educational approaches will be needed, tailored to the needs of specific populations and designed to effectively educate individuals with lower health literacy. The roll-out of HIVST may also necessitate the revision of existing HIV-related educational materials, for example, by expanding on information regarding the window period for the diagnosis of HIV.

HIVST pilot studies indicate that some individuals and groups are unlikely to utilize HIVST without supporting interventions to increase the dissemination of HIV self-test kits and to facilitate access (48,64). Community resources should be fully leveraged to encourage utilization of HIVST, especially for key populations and those not served by traditional services (31).

8. Fast-Track Cities and stakeholders should optimize service delivery to welcome into clinical services people who self-refer after HIVST.

HIVST results, whether positive or negative, should be accepted at face value, with additional confirmatory tests performed in accordance with the recommended algorithm. Fast-Track Cities should develop educational programs on HIVST for healthcare providers.

Rationale

At-home pregnancy testing – now regarded as an uncontroversial diagnostic tool – met with resistance from healthcare workers when it was first introduced (65). Unless proactive measures are put in place to educate and sensitize healthcare workers, similar resistance to HIVST is likely to emerge, slowing the uptake of HIVST and hindering essential linkages to care.

In particular, steps are needed to ensure that clinics and healthcare providers accept HIVST results and make those providing these results feel welcome. Consistent with a people-centered approach, service delivery systems should be adapted to HIVST as an important new tool to increase knowledge of HIV status and facilitate linkage to and uptake of HIV treatment and prevention services. (15).

9. Fast-Track Cities should remove technical and administrative barriers to improve access to HIV self-tests.

Fast-Track Cities should prevent imposition of technical requirements or administrative approvals that might deter utilization of HIVST (e.g., requirements for supervision, linkage to care, for users to answer questions or participate in studies, for partner notification services to be in place). This includes increased availability and expanded access to “no strings attached” HIVST through good-quality, affordable (preferably no or minimal cost), non-traditional outlets.

Rationale

As people at risk of HIV infection vary widely in their preferences for HIV testing settings and approaches (43,44), Fast-Track Cities should facilitate the widest possible array of service delivery channels and strategies for HIVST. Technical requirements, including the need to guarantee linkage to care, participate in research to access the tests, or for partner notification, can delay rapid implementation and access to HIV self-test kits. In addition to encouraging over-the-counter sales of HIV self-test kits, promising strategies for distribution of HIV self-test kits include community-based outlets, vending machines (66), online distribution (67), bathhouses or other venues where key populations congregate (68), and HIV and other community-based or support organizations.

Fast-Track Cities should ensure increased availability and expanded access to “no strings attached” HIVST through good-quality, affordable non-traditional outlets.

Conclusion

As the above discussion indicates, the public health potential of HIVST will not be fully realized without strong commitment, smart programming, and ongoing monitoring and programmatic adaptation. Fast-Track Cities are ideally positioned to catalyze rapid uptake of HIVST and to ensure that this new tool reaches those most in need as quickly as possible, given decisive, time-delimited targets. These recommendations are intended to assist Fast-Track Cities in taking immediate action to promote HIVST and to make it widely available as part of accelerated local AIDS responses, and in support of attaining the 90-90-90 targets. Toward this end, Fast-Track Cities are encouraged to make strategic use of available technical support, including but not limited to support available through the Fast-Track Cities initiative, as well as WHO and other relevant stakeholders.

The public health potential of HIVST will not be fully realized without strong commitment, smart programming, and ongoing monitoring and programmatic adaptation. Fast-Track Cities are ideally positioned to catalyze rapid uptake of HIVST and to ensure that this new tool reaches those most in need as quickly as possible, given decisive, time-delimited targets.

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APPENDIX 1

HIV Self-Tests on the Market

Table A1. Specifications for HIV Self-Tests on the Market^f

The adapted Table below reflects information shared by the manufacturers with UNITAID and through public evaluations of HIV rapid diagnostics tests (RDTs) by a founding member of the Global Harmonization Task Force on Medical Devices (GHTF). Sensitivity and specificity denote the performance in the hands of self-testers and the performance in the hands of professional users. The information was provided by the manufacturers and reflects what is stated in the manufacturers' information for users and what is reported by recognized regulatory authorities (e.g., FDA, CE, Therapeutic Goods Administration [TGA], Australia) or other international approval systems (e.g., WHO prequalification, Global Fund, United States Agency for International Development [USAID]). Sensitivity and specificity reported in the literature but not recognized by a regulatory authority is not reflected. This is a dynamic area and we urge those interested to contact the manufacturers directly to gather the most up-to-date information.

Name	Autotest VIH®	BioSURE HIV Self Test	INSTI HIV Self Test	OraQuick® In-Home HIV Test
Company/location	AAZ-LMB/ RungisCedex, France	BioSURE UK Ltd/ United Kingdom	bioLytical Laboratories/ Richmond, BC, Canada	OraSure Technologies LLC/ Bethlehem PA, USA
Professional test basis (commercial professional use name-trademark)	SURE CHECK® HIV-1/2; STAT-VIEW HIV-1/2	SURE CHECK® HIV-1/2; STAT-VIEW HIV-1/2	INSTI HIV-1/HIV-2 antibody test kit	OraQuick Advance Rapid HIV 1/2 antibody test
Approvals for professional use	CE/FDA ^g	CE/FDA ^g	CE/FDA/HealthCanada/ WHO prequalification ^h	FDA/CE/WHO prequalification ^h
Approvals for HIVST	CE, WHO prequalification submitted 2016	CE	CE	FDA (not marketed in EU)
Technology	Lateral flow	Lateral flow	Immunofiltration	Lateral flow
Ag type/control	Synth gp36, gp41, gp120/ Control: protein A	Synth gp36, gp41, gp120/ Control: protein A	Gp41, gp36 Control: protein A	Synthetic peptides representing HIV envelope
Output	Qualitative immunoassay HIV 1/2 antibody detection	Qualitative immunoassay HIV 1/2 antibody detection	Qualitative immunoassay HIV 1/2 antibody detection	Qualitative immunoassay HIV 1/2 antibody detection
Sens/Spec/Invalid	100%/99.8%/0.8%	99.7%/99.9%/0.16%	100%/99.8%/0%	FDA: 91.7%/98.7%/1.1% CE: 100%/98.7%/1.8%

^f The above specifications table was adapted from UNITAID's resource document Technology landscape: HIV rapid diagnostic tests for self-testing (2nd edition), 1 July 2016 (53) (http://unitaid.org/images/marketdynamics/publications/UNITAID_HIV_rapid_diagnostic_tests_for_self-testing.pdf.) This is a dynamic area and we urge those interested to contact the manufacturers directly to gather the most up-to-date information.

^g <http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/PremarketApprovalsPMAs/ucm091240.htm>

^h http://www.who.int/diagnostics_laboratory/evaluations/161214_prequalified_product_list.pdf?ua=1

Sample/volume	Capillary whole blood/ 2.5 µL	Capillary whole blood/ 2.5 µL	Capillary whole blood/ 50 µL	Oral fluid/swab
Capacity	Single/Single use	Single/Single use	Single/Single use	Single/Single use
Buffer volume	150–200 µL	150–200 µL	1.5 mL × 3 (diluent, developer, clarifying)	1 mL
Time to result	15 minutes	Not before 15 min	Instant	Not before 20 minutes
Read window	Not after 60 minutes	Not after 60 minutes	Not after 5 minutes	Not after 40 minutes
Protocol complexity (no. of steps)	5	3	5	5
Shelf-life	24 months	24 months	15 months	30 months
Storage requirements	8–30 °C/ no direct sunlight	8–30 °C/ no direct sunlight	15–30 °C	2–30 °C
Not included in kit	Timer	Timer	Timer not required	Timer
Restrictions	Not for use while on ARVs	Not for use while on ARVs	Not suitable for bleeding disorder, below 18 years, using ARVs, participants in HIV vaccine study	<15 minutes: No eating, drinking, chewing gum; <30 minutes no mouth cleaning products; not for use while on ARVs
Price per test	US\$ 25–28 consumer price in Europe	US\$ 42–48 recommended retail (including tax)	\$36 recommended price in Europe	Distributor NA Rec. retail in US is \$40
Price per test NGOs and distributors	US\$ 8–15	US\$ 7.50–12.00 for sale in public sector including UK NGOs	Cost depends on order size (e.g., test on offer for \$3.00 for bulk sales in Africa)	No pricing outside USA for NGOs or distributors
Additional	No formal evaluation for use with PrEP/PEP	No formal evaluation for use with PrEP/PEP	No formal evaluation for use with PrEP/PEP	Detects 2.5 days later than EIA assay; no formal evaluation for use with PrEP/PEP

Note: Autotest VIH (AAZ, France) and BioSURE HIV Self-test (UK) are similar rapid HIV tests, which means that there are three types of HIV self-tests available: INSTI, OraQuick and SURE CHECK®. However, Sure Check does not have HIV self testing as an approved intended use. The Sure Check brand is solely for professional in the USA. The device has been placed on the market in the EU for professional use only under the STAT-VIEW® HIV 1/2 Assay brand.

Ag: antigen; ARV: antiretroviral; CE: Conformité Européenne; EIA: enzyme immunoassay; EU: European Union; FDA: U.S. Food and Drug Administration; gp: glycoprotein; NA: not available; NGO: non-governmental organization; PrEP: pre-exposure prophylaxis; PEP: post-exposure prophylaxis; sens: sensitivity; spec: specificity; synth: synthetic; UK: United Kingdom

APPENDIX 2

Search Strategy for Recommendationsⁱ

SEARCH 1	SEARCH 2	SEARCH 3
<p>MEDLINE (OVID) * = focus of MeSH term / = index term (MeSH) ti = title ab = abstract adj = adjacency \$ = truncation of root word</p> <p>HIV keywords and MeSH</p> <ol style="list-style-type: none"> 1. *HIV infections/ 2. *HIV seropositivity/ 3. *AIDS serodiagnosis/ 4. HIV.ti,ab 5. or/1-4 <p>Self/Home Testing keywords and MeSH</p> <ol style="list-style-type: none"> 6. *Self Care/ 7. *Self Administration/ 8. *Diagnostic self evaluation/ 9. *Reagent kits, diagnostic/ 10. (self adj4 test\$.ti,ab 11. (home adj4 test\$.ti,ab 12. (rapid adj4 test\$.ti,ab 13. (HIVST or HST).ti,ab 14. or/6-13 15. 5 and 14 <p>Limited to published years = 2000 – present</p>	<p>OVID EMBASE HIV keywords and index terms</p> <ol style="list-style-type: none"> 1. *Human immunodeficiency virus infection/ 2. *Human immunodeficiency virus/ 3. *Serodiagnosis/ 4. *HIV test/ 5. HIV.ti,ab 6. or/1-5 <p>Self/Home Testing keywords and index terms</p> <ol style="list-style-type: none"> 7. *Self care/ 8. *Self evaluation/ 9. *Diagnostic kit/ 10. (self adj4 test\$.ti,ab 11. (home adj4 test\$.ti,ab 12. (rapid adj4 test\$.ti,ab 13. (HIVST or HST).ti,ab 14. or/7-13 15. 6 and 14 16. Limit 15 to conference abstracts.pt 17. 15 NOT 16 <p>Limited to published years = 2000 – present</p>	<p>EBSCOhost CINAHL MM = CINAHL Heading, Major Concept TI = title AB = abstract N4 = adjacency search, Near/Within 4 terms * = truncation of root word</p> <p>HIV keywords and CINAHL Indexing</p> <ol style="list-style-type: none"> 1. (MM "HIV Infections") 2. (MM "HIV Seropositivity") 3. (MM "AIDS Serodiagnosis") 4. TI HIV OR AB HIV 5. or/1-4 <p>Self/Home Testing keywords and CINAHL Indexing</p> <ol style="list-style-type: none"> 6. (MM "Self Care") 7. (MM "Self Administration") 8. (MM "Home Diagnostic Tests") 9. (MM "Reagent Kits, Diagnostic") 10. TI self N4 test* OR AB self N4 test* 11. TI home N4 test* OR AB home N4 test* 12. TI rapid N4 test* OR AB rapid N4 test* 13. TI HIVST OR AB HIVST 14. TI HST OR AB HST 15. or/6-14 16. 5 and 15 <p>Limited to published years = 2000 – present</p>

SEARCH 4

PubMed Search
 * = truncation of root word
 Limited to publication after January 1, 2015

((self test*[Title/Abstract]) OR (home test*[Title/Abstract]) OR (rapid test*[Title/Abstract])) AND (hiv[Title/Abstract]) AND ("2015/1/1"[Date - Publication] : "3000"[Date - Publication])

ⁱ All searches performed on October 12, 2016

APPENDIX 3

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APPENDIX 4

HIV Self-Testing Resources

Resources

African Society for Laboratory Medicine (ASLM)
<http://www.aslm.org/>

Centers for Disease Control and Prevention Home HIV Tests
<https://www.cdc.gov/hiv/testing/hometests.html>

Fast-Track Cities
www.fast-trackcities.org

International Association of Providers of AIDS Care (IAPAC)
<http://www.iapac.org/>

UNITAID
<http://www.unitaid.eu/en/>

IAPAC 2015 Guidelines
<http://www.iapac.org/uploads/IIAPAC-IAPAC-Guidelines-for-Optimizing-the-HIV-Care-Continuum-Supplement-Nov-Dec-2015.pdf>

WHO 2015 ART Guidelines
<http://www.who.int/hiv/pub/guidelines/earlyrelease-arv/en/>

WHO 2016 HIVST Guidelines
<http://www.who.int/hiv/pub/vct/hiv-self-testing-guidelines/en/>

IAPAC HIV 90–90–90 Watch
www.HIV90-90-90watch.org

IAPAC HIV Policy Watch
www.HIVpolicywatch.org

APPENDIX 5

List of Priority Fast-Track Cities^j

AFRICA

Abidjan (Côte d'Ivoire)	Kigali (Rwanda)
Accra (Ghana)	Kinshasa (Democratic Republic of the Congo)
Algiers (Algeria)	Lagos (Nigeria)
Bamako (Mali)	Libreville (Gabon)
Blantyre (Malawi)	Lilongwe (Malawi)
Brazzaville (Congo)	Lusaka (Zambia)
Casablanca (Morocco)	Maputo (Mozambique)
Cotonou (Benin)	Nairobi (Kenya)
Dakar (Senegal)	Ouagadougou (Burkina Faso)
Dar es Salaam (Tanzania)	Ouessou (Republic of Congo)
Djibouti (Djibouti)	Pretoria (South Africa)
Douala (Cameroon)	Windhoek (Namibia)
Durban (South Africa)	Yaoundé (Cameroon)
Johannesburg (South Africa)	

LATIN AMERICA / CARIBBEAN

Buenos Aires (Argentina)	Quito (Ecuador)
Curitiba (Brazil)	Rio de Janeiro (Brazil)
Havana (Cuba)	Salvador de Bahia (Brazil)
Kingston (Jamaica)	São Paulo (Brazil)
Mexico City (Mexico)	Santa Fe (Honduras)
Montevideo (Uruguay)	Santiago (Chile)
Panama City (Panama)	San Miguelito (Panama)
Port-au-Prince (Haiti)	

EUROPE

Amsterdam (Netherlands)	Geneva (Switzerland)
Athens (Greece)	Kyiv (Ukraine)
Barceona (Spain)	Madrid (Spain)
Berlin (Germany)	Paris (France)
Brussels (Belgium)	Seville (Spain)
Bucharest (Romania)	

ASIA / ASIA-PACIFIC

Bangkok (Thailand)	Melbourne (Australia)
Delhi (India)	Mumbai (India)
Jakarta (Indonesia)	

NORTH AMERICA

Atlanta (USA)	New York City (USA)
Baltimore (USA)	Oakland (USA)
Denver (USA)	Phoenix (USA)
Mexico City (Mexico)	Providence (USA)
Miami (USA)	San Francisco (USA)
New Orleans (USA)	Washington, DC (USA)

^j As of January 15, 2017





www.fast-trackcities.org

www.iapac.org

www.aslm.org