

HIV Self-Testing Quick Reference Guide

HIVST IN PRACTICE

When should HIV self-testing be used rather than conventional testing approaches?

Where are the gaps?

What is the potential impact?

HIV self-testing (HIVST) should be highly targeted to **individuals in groups not currently being reached by existing HIV testing services (HTS)**. HIVST distribution approaches should be tailored to populations with low testing coverage and at ongoing HIV risk. **For highest impact and cost effectiveness, HIVST should not replace conventional HTS but should be used to:**

- 1. Improve access for people with high HIV risk and vulnerability**, including people living with HIV who have been lost to follow-up (PLHIV LTFU), people who do not currently use HTS, adolescents, and hard-to-reach key populations.
- 2. Facilitate partner testing and index testing** by providing kits to people with HIV or at high risk of HIV so that they can offer HIVST to their partners or other people in their social networks.
- 3. Improve testing coverage by integrating it into clinical services** where testing is needed but not routinely provided or where testing is poorly implemented. **If the price of HIVST kits were to fall below \$1 per test, then PEPFAR would support the targeted use of HIVST at health facilities.** In this context, HIVST can replace components of provider-initiated HIV testing. Offering HIVST at high-volume clinics in high-HIV-burden settings and at sexually transmitted infection (STI) or family planning clinics makes efficient use of clients' waiting time and ensures links to care services.
- 4. Create demand and increase uptake of HIV prevention services.** Those with a nonreactive self-test result will not need confirmatory testing, but HIVST is an opportunity to direct these people to prevention services (e.g., pre-exposure prophylaxis [PrEP], voluntary medical male circumcision [VMMC], condoms, and STI screening/treatment).

EpiC is a global cooperative agreement dedicated to achieving and maintaining HIV epidemic control. It is led by FHI 360 with core partners Right to Care, Palladium International, Population Services International (PSI), and Gobe Group.

WHO?

Who are the target populations? Who could benefit from HIVST?

HIVST has the greatest impact when targeted at members of populations who do not access other forms of HTS.

The World Health Organization (WHO) and U.S. President's Emergency Plan for AIDS Relief (PEPFAR) have identified several populations as high priority for HIVST:

- Adult men in high-HIV-burden settings
- Adolescents and young people (ages 15–24 years) in high-HIV-burden settings
- PLHIV LTFU, as an easy way to re-enter treatment services
- Key populations: men who have sex with men (MSM), people who inject drugs (PWID), sex workers (SWs) and their sexual partners, transgender women, and people in prisons
- Other high-risk groups, including STI patients; women presenting for family planning services in high-burden settings; couples and partners, including partners of PLHIV; refugees; young at-risk men; and other groups that face high levels of stigma and discrimination

There may be other target groups depending on the country's HTS and antiretroviral therapy (ART) gaps.

AGE OF CONSENT FOR HIVST AND HIVST WITH YOUNG ADOLESCENTS

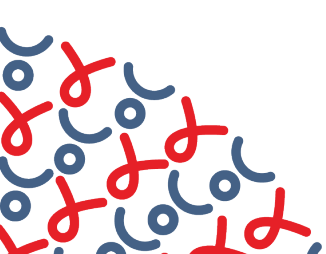
In most countries, the age of consent for HIV testing is 16 and this would also apply to HIVST.

In countries with the age of consent at 12–15 years (young adolescents), HIVST should always be assisted by a trained health care provider.

HIVST has a high acceptance rate among older adolescents and youth, and adolescents are more likely to accurately use oral self-test kits. Although HIVST holds potential to increase HTS coverage among adolescents, programs will need to ensure that adolescents who screen positive are linked to diagnostic HTS and treatment services, if confirmed positive.

USE OF RAPID HIV-1/2 SALIVA-BASED ANTIBODY TESTS IN CHILDREN 2–11 YEARS

Studies have shown that rapid HIV-1/2 saliva-based antibody tests have high sensitivity and specificity in children older than 2 years, and these tests have been approved by WHO for use in children starting at age 2 up to age 11 with the assistance of a trained health care worker.



WHAT?

Once national policy frameworks are in place, adequate HIVST service delivery requires careful planning. Effective HIVST approaches are based on three main components:

1. Demand creation and client mobilization
2. HIV testing process
3. Linkage process after HIVST

CORE HIVST PROGRAM COMPONENTS

1. **Demand creation/mobilization:** A comprehensive, user-centered communications and marketing strategy should increase awareness and demand among priority populations and engage with key stakeholders.
2. **Testing process:** Distribution is either direct (offered to the client who will use it) or indirect (offered to an intermediary) and can be unassisted or assisted—when a trained provider or peer gives information on how to use the kit and interpret the result and demonstrates use before giving it to the client. Self-test users can test on site or take the test kit home.
3. **Linkage:** Have tools available that support testers' links to counseling, treatment, and/or prevention after a self-test. Tools should allow the tester to opt-in, use the highest level of technology available to the target population (e.g., phone, Internet, smartphone), offer the option of speaking to a human and direct community follow-up, and protect the privacy and confidentiality of the self-testing experience.

Tools should not pressure self-testing clients to disclose their test results nor compromise the privacy of the testing experience. People who use a self-test kit at a facility or community event should be offered confirmatory testing and linkage services on site. Linking self-testers who test off site is more challenging, so innovative follow-up approaches, such as calls, SMS, WhatsApp contact, or community outreach, might be required. The STAR Initiative has developed a range of tools to support linkage, available at: <http://hivstar.lshtm.ac.uk>. Also see, USAID resources, available at: <https://aidsfree.usaid.gov/resources/hts-kb/hiv-self-testing/all>.

HIVST KITS

Where can HIVST kits be procured?

There are currently four WHO prequalified HIVST products:

- OraQuick HIV Self-Test (OraSure Technologies, USA); oral fluid
- INSTI HIV Self-Test (Bioanalytical, Canada); blood-based
- Mylan HIV Self-Test (Mylan, Atomo Diagnostics, Australia); blood-based
- SURE CHECK HIV 1/2 Assay (Chembio, USA), blood-based

All four kits can be procured with U.S. Government or Global Fund funds. To order, contact the Global Health Supply Chain-Rapid Test Kits (GHSC-RTK) via Dianna Edgil (dedgil@usaid.gov).

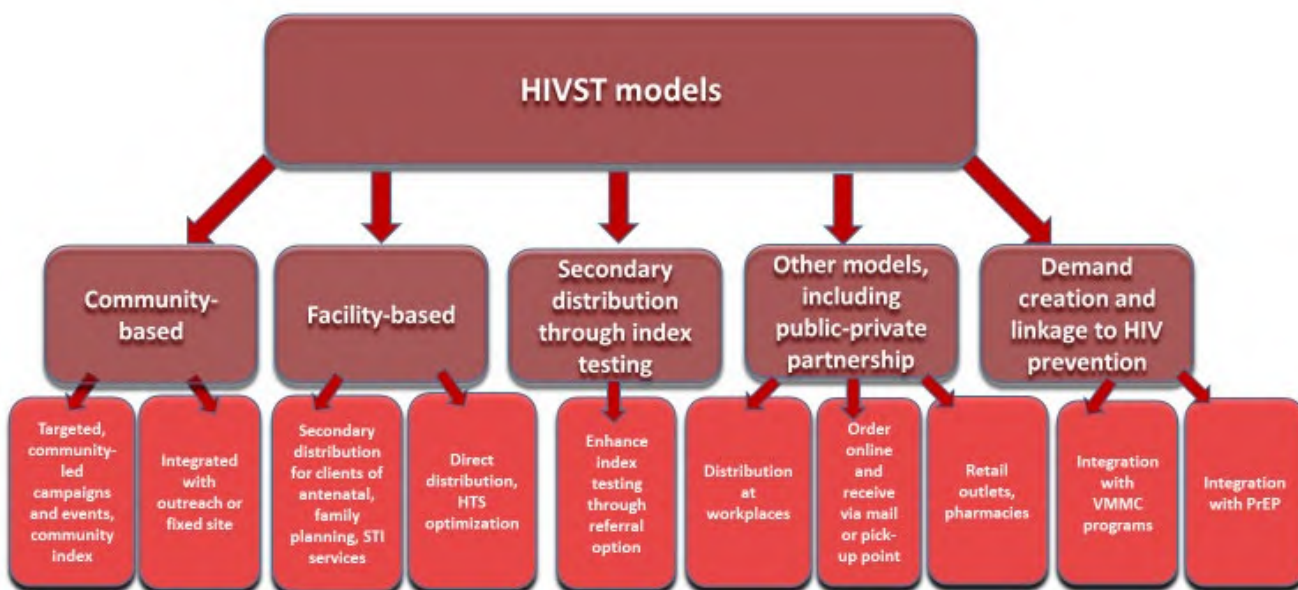
Selecting HIVST products for procurement from WHO’s lists of prequalified HIVST kits will enable countries to forgo in-country performance evaluations. HIVST products for procurement can be identified by reviewing those listed at the following links: [WHO prequalification](#) and [GF Quality Assurance Policy for Diagnostic Products](#).

HOW?

There are many effective HIVST delivery mechanisms, in which individuals either test by themselves in private or distribute tests to partners and social contacts.

The diagram below depicts the most frequently used HIVST distribution approaches. Evidence summarized by WHO demonstrates they all work in different contexts. Implementation arrangements must be tailored to the target population group and responsive to their preferences.

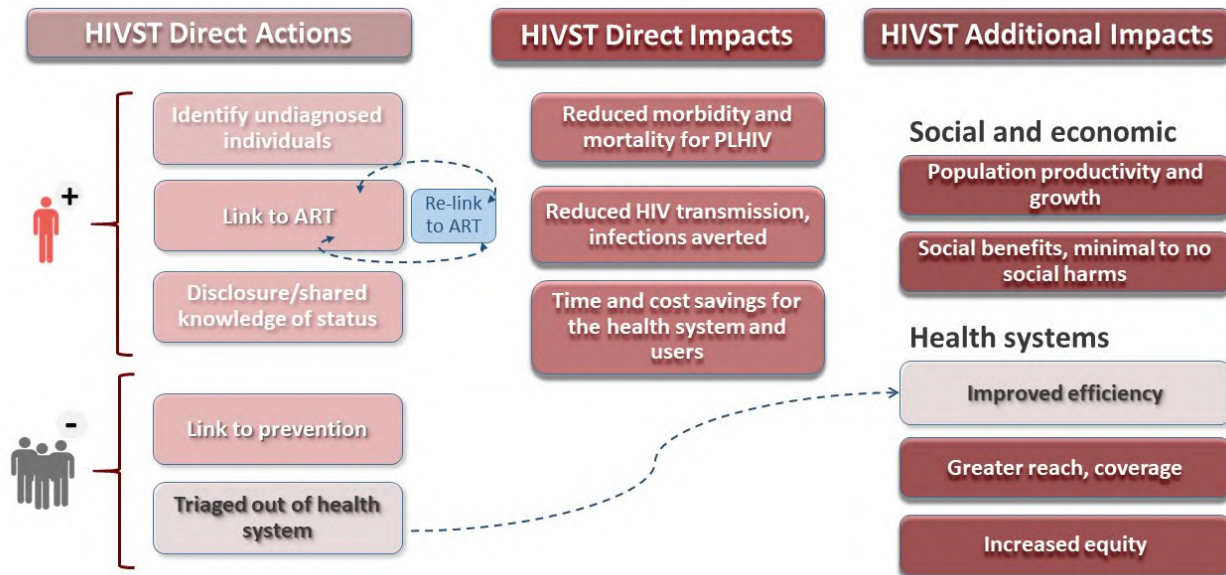
For help selecting optimal distribution models for the country context and health system structures, USAID Missions can contact Vincent Wong (vwong@usaid.gov) or Elisabeth Manfredini (emanfredini@usaid.gov) or access technical assistance through the EpiC (Judy Chen, juchen@usaid.gov) or RISE (Jacquie Firth, jfirth@usaid.gov) projects.



IMPACT FRAMEWORK

Investments in HIVST can result in broad health and social benefits.

HOW HIVST AFFECTS INDIVIDUALS, POPULATIONS, AND SYSTEMS



MONITORING AND EVALUATION

How should HIVST outcomes and impact be measured and reported?

Several indicators are recognized by WHO and PEPFAR for monitoring HIVST. Many of these metrics can be obtained using routine clinic data to provide a picture of HIVST’s reach, outcomes, links to care and prevention, and measures of process efficiency. STAR sample monitoring tools can be found at:

- <http://hivstar.lshtm.ac.uk>
- <https://aidsfree.usaid.gov/resources/hts-kb>
- <https://www.who.int/hiv/pub/self-testing/strategic-framework/en/>

MONITORING, EVALUATION, AND REPORTING (MER) INDICATORS

MER now includes an HTS_Self indicator to apply to HIVST kit distribution (required) and, where possible, use (recommended). Disaggregates of HTS_Self include age/sex of recipient, point of distribution, intended use (primary or secondary distribution); see <https://www.state.gov/wp-content/uploads/2019/10/PEPFAR-MER-Indicator-Reference-Guide-Version-2.4-FY20.pdf>.

SPECIFIC HIVST INDICATORS

Reach

Which distribution strategies are most effective for reaching the priority populations?

- Uptake of HIVST by priority populations: adult males, adolescent girls and young women, adolescent boys and young men, key populations, other unreached populations
- HIV testing coverage among priority populations
- HIV testing uptake among index cases after HIVST

Reach data are:

- Disaggregated by sex and age
- Disaggregated by testing history (most recent test in the past three months, past 12 months, never tested)
- Disaggregated by approach (e.g., community-based, facility-based, secondary distribution)
- Type of sites (e.g., community outreach, door-to-door, mobile, workplace, antenatal clinic, primary care, outpatient department, STI clinic, family planning clinic)
- Self-testing by self, sex partner, other

Outcome of HIVST

- Measuring impact of HIVST on reaching the undiagnosed, links to HIV care/treatment and prevention after HIVST
- Reactive and nonreactive (negative) HIVST results can either be collected through directly assisted, on-site HIVST or—if HIVST was conducted off site or the recipient received the test through secondary distribution—via direct follow-up with the self-tester.

Links to HIV care after HIVST

- Uptake of confirmatory testing (can be measured if self-testing is incorporated in clinic data or through direct follow-up of self-test users)
- ART initiation after HIVST (needs to be standardized, per clinic/day ideally)

Links to prevention services, VMMC, and PrEP uptake after HIVST

- Uptake of VMMC services after HIVST
- Uptake of PrEP services after HIVST

Process efficiency

- Measure different steps in the distribution and linkage processes for each of the distribution models to identify bottlenecks and to ensure fidelity of the planned HIVST service delivery approaches.

NOTE: Implementers should attempt to track adverse events associated with HIVST, including instances of self-harm and events related to secondary distribution, where possible.