



FDA Regulation of HIV Self-Testing Devices and Self-Collection Kits for HIV Diagnosis

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**In Vitro Diagnostic
devices are
medical devices
per 201(h) of
Food, Drug, &
Cosmetic (FD&C)
Act [21 CFR 809.3]**

Medical devices are

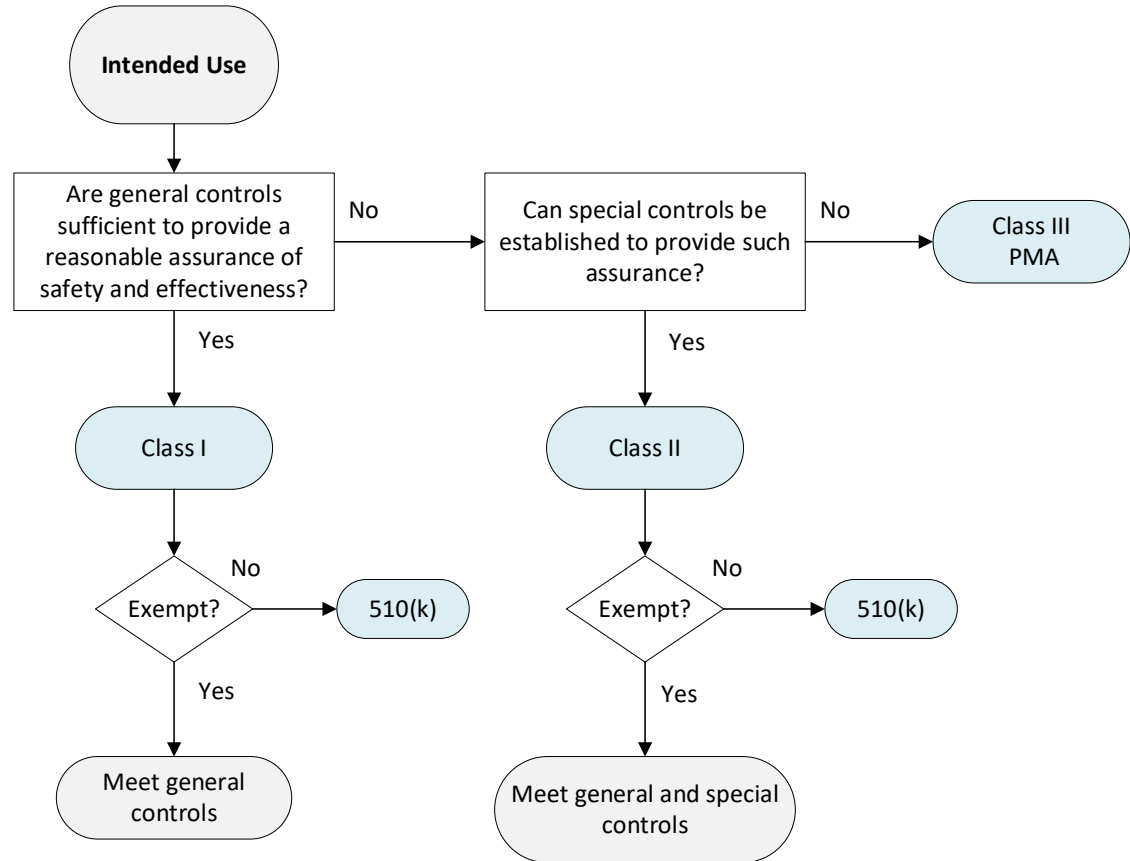
- Reagents, instruments, and systems used in diagnosis of disease or other conditions...in order to cure, mitigate, treat, or prevent disease
- Intended for use in the collection, preparation, and examination of specimens taken from the human body



Review of IVDs is based on:

The balance of
benefit/risk to the
individual

A reasonable assurance
of safety and
effectiveness of the
device





FDA regulation of HIV Self-Testing devices

HIV Self-Testing (HIVST) devices are class III medical devices

HIVSTs require approval of a PMA before they can be marketed

- There is one approved self-testing device (OraQuick HIV in-home test, approved in 2012)
- HIVST were not included in the reclassification of HIV diagnostic, supplemental, or viral load tests due to a lack of sufficient experience with these devices to write special controls

However

- FDA agrees that there is an urgent need to improve access to HIVST
- FDA is working with manufacturers and will consider alternative validation strategies, e.g., based on the regulatory status of the device (approved PoC claim vs. no approved claim) to expedite entry to market



FDA regulation of HIV self-collection kits

HIV self-collection kits require FDA approval

Self-collection kits are medical devices

- Review pathway is determined by the Intended Use (e.g., home use or clinic; supervised or unsupervised, etc.)

Adequate and appropriate sample collection is essential for a device to meet performance expectations

- Self-collection → untrained individual collects their own sample
- No automatic assurance that collection has been performed appropriately
- FDA reviews instructions for sample collection and the device's performance with the intended sample type to ensure a reasonable assurance of safety and effectiveness of the device

Current landscape

FDA recognizes there is a need for self-collection kits for HIV diagnosis for individuals unable or unwilling to attend a clinic

But

- HIV self-collection kits require approval of a PMA* to comply with the FD&C Act
- Distribution of unapproved HIV self-collection kits is a violation of the Act#
- There are no FDA-approved HIV self-collection kits that use blood samples currently on the market

FDA's goal is to bring unapproved/uncleared devices into compliance with the law and regulations, and in the interest of public health, FDA is committed to working with device developers to meet the requirements

* Or clearance of a 510(k) following reclassification of HIV diagnostic devices

See 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B); 502(o) of the Act, 21 U.S.C. § 352(o); and 301(k) of the Act, 21 U.S.C. § 331(k)



Thank you!

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DETTD/OBRR/CBER
FDA

Turning the Tide on Self-Testing and Sample Collection

Background and Need

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Nothing to Disclose

The findings and conclusions in this presentation are those of the author and do not necessarily represent the views of the U.S. Centers for Disease Control and Prevention (CDC).

Use of trade names is for identification purposes only and does not constitute endorsement by the CDC or the US Department of Health and Human Services.



Terminology

- **Point of Care Test (POC)** – Conducted near an individual also referred to as point of contact or rapid tests administered by trained staff or health care providers
- **Self-Test** -a complete test conducted by an individual for their own knowledge- also referred to as an over- the -counter test (OTC) or direct to consumer test (DTC)
- **Self-collection (self-collected test)** - a scenario where an individual collects their own sample, and hands it off or ships the sample to a laboratory for testing

Considerations for Self-testing or Self-collection Testing

- Important for populations where Clinic/Lab testing is difficult or not feasible
- Important to provide clear information regarding assay limitations
 - Oral Fluid assays will miss acute infections and some early infections ^{2,3,4}
- Are used in conjunction with clinical testing for a definitive diagnosis
- Ideally at a price point that will allow wide access

^{1,2}Stekler et al, JCV 2013 and 2016, ³Luo et al JCV 2013

Self Test Availability and Limitations

■ HIV

- One test is FDA approved (OraQuick- July 2012)
- Oral Fluid
- Cost ~ \$35.00-\$40.00 retail
- Does not detect acute HIV infections (up to 90 days for positive result post infection)
- Limitations for use in context of PrEP (delayed reactivity in PrEP trials and not optimal for prescribing PrEP)

■ STIs

- No FDA cleared tests

■ Viral Hepatitis

- No FDA cleared tests



<https://www.cdc.gov/hiv/testing/self-testing.html>

Self-testing Data HIV U.S.

- **Data indicate there is a benefit to this approach**
 - **eSTAMP CDC/Emory large longitudinal randomized clinical trial (RCT) of MSM (N=2665) ¹**
 - **Demonstrated feasibility, acceptability and benefit of distribution of self-tests kits**
 - **Oral Fluid FDA approved test (OraQuick), Fingerstick test under IDE (Sure Check), Feasibility of Dried Blood Spot (DBS)**
 - **Identified infection in first time testers and social contacts**
 - **No harmful adverse events**
- **Partnership with CDC's Let's Stop HIV Together Campaign-to launch TakeMeHome ²**
 - **Distributed ~ 100,000 HIV free self-test kits through the portal at <https://together.takemehome.org/>**
 - **Demonstrated self-testing serves people who might be reluctant or unable to seek clinic- or community-based testing**
- **80% of the jurisdictions that are part of the Ending the HIV Epidemic in the U.S. indicated this tool is important for their community EHE plans**

¹ MacGowan et al. JAMA Intern Med, 2019 ²<https://www.cdc.gov/mmwr/volumes/70/wr/mm7038a2.html>

WHO recommendations on HIV self-testing



Key evidence showed HIVST is:

- Safe and accurate
- Highly acceptable
- Increased access
- Increased uptake and frequency of **HIV testing among those at high risk and who may not test otherwise**
- Comparable linkage and HIV+
- Empowering
- Can be affordable and cost-effective when focused

WHO recommendation:

HIV self-testing should be offered as an approach to HIV testing services

(strong recommendation, moderate quality evidence)

NEW remarks

- Providing HIVST service delivery and support options is desirable.
- Communities need to be engaged in developing and adapting HIVST models.
- HIVST does not provide a definitive HIV-positive diagnosis.

WHO recommends HIV self-testing. (2016) World Health Organization. <https://apps.who.int/iris/handle/10665/251549>
Consolidated guidelines on HIV testing services. <https://www.who.int/publications/i/item/978-92-4-155058-1>

HIVST products with WHO prequalification

Test (manufacturer)	Type
INSTI® HIV Self Test ** (bioLytical Lab., Canada)	Blood
Mylan HIV Self Test	Blood
OraQuick® HIV Self Test (OraSure Technologies, USA)	Oral
SURE CHECK® HIV Self Test (Chembio Diagnostic Systems Inc., USA)	Blood

Global Fund HIVST pricing
US\$ 2-3.10

More information available from
Global Fund PSM/Sourcing
team



CE Marked Tests	Type
Simplitude ByMe HIV Self Test	Blood
Mylan HIV Self-test	Blood
INSTI	Blood
BioSure	Blood
OraQuick	Oral Fluid



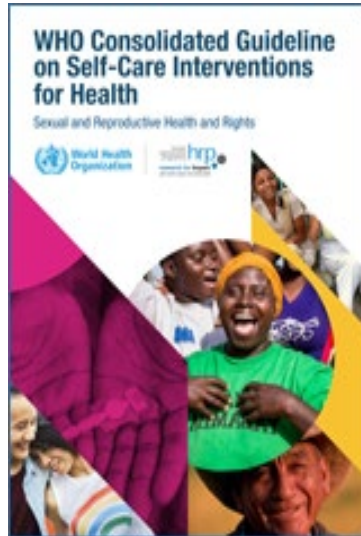
Latest list of WHO prequalified products: https://www.who.int/diagnostics_laboratory/evaluations/PQ_INST/en/

Self Sample Collection

- **No FDA cleared(STI/Hepatitis tests)/approved (HIV) tests for self-collection and submission to a laboratory**
 - Previous HIV Self-collection test - Home Access no longer on the market
- **Commercial labs have set-up this service (Lab developed tests (LDT)).**
 - Testing during COVID for HIV and STIs for PrEP
 - Hepatitis B and C antibody tests
- **Multiple Studies on STI Self-collection inside and outside the U.S.**
 - WHO funded Meta-analysis¹
 - Programs offering self-collection of samples increased the overall uptake of STI testing services

¹Ogale et al. BMJ Glob Health 2019

STI Self-Collection-WHO



4. Combating sexually transmitted infections, including HIV, reproductive tract infections, cervical cancer and other gynaecological morbidities

New recommendation on HPV self-sampling

REC 21 (NEW): HPV self-sampling should be made available as an additional approach to sampling in cervical cancer screening services for individuals aged 30–60 years.

Strong recommendation,
moderate-certainty evidence

New recommendation on self-collection of samples for STI testing

REC 22a (NEW): Self-collection of samples for *Neisseria gonorrhoeae* and *Chlamydia trachomatis* should be made available as an additional approach to deliver STI testing services for individuals using STI testing services.

Strong recommendation,
moderate-certainty evidence

REC 22b (NEW): Self-collection of samples for *Treponema pallidum* (syphilis) and *Trichomonas vaginalis* may be considered as an additional approach to deliver STI testing services for individuals using STI testing services.

Conditional recommendation,
low-certainty evidence

Existing recommendation on HIV self-testing

REC 23: HIV self-testing should be offered as an additional approach to HIV testing services.

Strong recommendation,
moderate-quality evidence

<https://pubmed.ncbi.nlm.nih.gov/31334932/>

Self-Collection STIs in U.S.

- **Some CT/NG tests have self-collection claims for clinical settings¹**
- **Data indicate self-collection can be as effective or better than clinician collected samples²**
- **Examples of Public Health Programs**
 - I Want the Kit STI testing <https://iwantthekit.org/> Johns Hopkins University
 - Chlamydia and gonorrhea -Maryland, Alaska and Arizona residents
 - GetCheckedDC: A Mail-in STI Testing Pilot Program- Washington D.C. <https://www.getcheckeddc.org/>
 - Both programs have reached priority populations and data indicate methodology is feasible

¹ Kersh et al: J Clin Microbiol, 2021

² Gaydos: Sex Transm Dis. 2018

Summary

■ HIV

- One FDA approved self-test
- Multiple tests available outside the U.S.
- Currently no FDA approved tests have a self-collection intended used claim
- FDA approved self-collection test for HIV for use with dried blood spots (DBS) previously available
- Data from eSTAMP supports self-collection and shipping of DBS

■ STI

- No FDA cleared tests with self-collection intended use outside of clinical settings
- Data indicate self sample collection can be as effective as clinician collected samples
- No FDA cleared STI self-tests

■ Self-testing and self collection of specimens

- Well accepted
- Can reach desired populations- reduced stigma
- Major adverse events have not been reported for self-testing or self-collection testing
- More general experience in populations due to SARS-CoV2 pandemic
- New technology due to SARS-CoV2

Questions for Discussion

1. **How important is self-testing and self-sample collection to overall public health efforts?**
2. **Are there specific analytes (e.g. antibody or antigen tests for HIV, HCV or treponemal/non-treponemal test for syphilis) that CHAC would consider a priority?**