

اختبار فيروس الإيدز

Le dépistage du VIH

艾滋病测试

La prueba del VIH

एच. आई. वी. परीक्षण

AIDS test

Translation isn't just about foreign language: Bridging the language gap with HIV testing

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Teste do VIH

HIV antibody test

HIV-Testen

HIV-1 Diagnostic Assay

VYA UKIMWI

Тестове за ХИВ

Mind the Gap

The availability of point-of-care HIV antibody tests has moved HIV testing out of the complex laboratory and into community-based settings. This has led to a need to bridge the gap between these lay organizations and the various entities involved in ensuring high quality laboratory testing, who are usually unfamiliar to community organizations.

We all share a common goal.

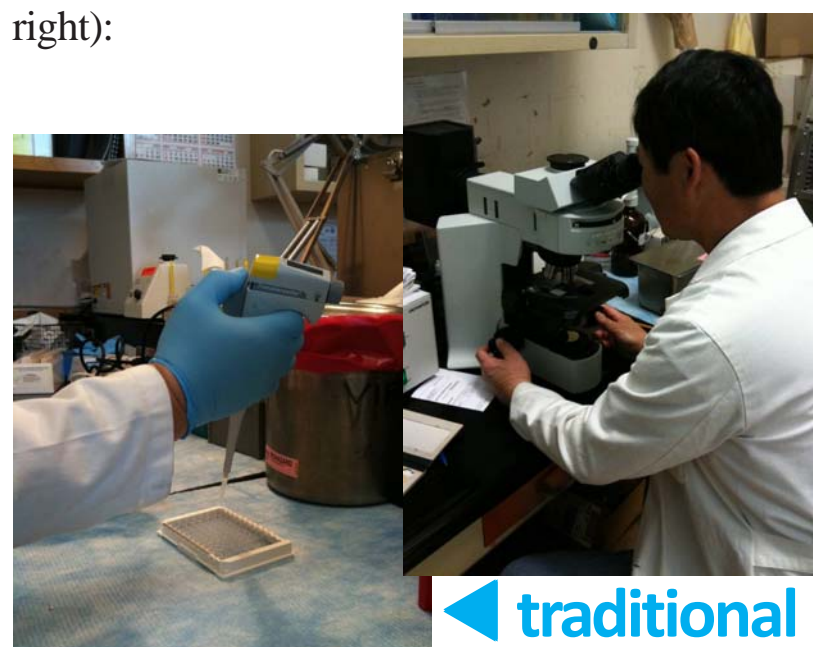
Laboratorians at both the local level and at the state laboratory level, program administrators at the local department of public health, officials at the FDA, CDC, and CMS, manufacturers of test kits, and lay counselors and technicians at POC test sites all share the common goal of high quality HIV testing.



Why the differences?

People in complex laboratories and in community organizations use different terminology and are familiar with different regulations and standards of practice, which can cause communication breakdown.

Just look at the differences in traditional laboratory settings (below), vs. non-traditional ones (at right):



traditional



non-traditional



Terminology is not just semantics.

We all use terminology that is familiar to us. Depending on our organization, education, and experience, the words we use feel commonplace.

But to others, the words are completely foreign. Take this example:

Entity	Language used
FDA	This test is a single-use qualitative immunoassay that detects antibodies to HIV-1 in a fingerstick sample of blood.
CDC	This test is a device cleared by the FDA and is determined to meet the criteria for waiver under CLIA.
CMS	This test is a simple laboratory procedure that has an insignificant risk of an erroneous result.
Test Kit Manufacturers	This test is intended for use as a point-of-care test to aid in the diagnosis of infection with HIV-1, and is suitable for use in multi-test algorithms designed for statistical verification of rapid HIV test results.
Public Health Departments	This is a screening test that, if reactive for HIV antibodies, is considered a preliminary positive result. A venipuncture confirmatory sample must be collected and sent to an off-site lab for confirmation.
Community organizations	This test looks for antibodies to HIV. Antibodies are the little soldiers your immune system develops in response to the virus. Only people with HIV develop these antibodies, which is why we can test this way.

What to do?

Common ground can be found between all these entities by identifying a person who can act as an intermediary between them. This must be a person who can move between worlds (i.e. is comfortable in a laboratory and understands the rules of CLIA but also has direct experience providing rapid HIV testing in a non-traditional test site). Most likely, this person is best based at the health department.



Put it in writing.

POC testing sites need guidance to develop protocols that are that are accessible and can be clearly understood by lay counselors while still addressing and satisfying all local, state, and federal testing requirements.

Putting it in writing makes it real – and gives everything the chance to ask questions and get clarifications right from the start. The intermediary is a key developer of this tool.

These protocols can be standardized and a template provided, which all sites can then customize to meet their needs.

It really works!

This strategy was used successfully in the city of San Francisco and has been replicated on a smaller scale in cities throughout the country. By implementing a strategy like this one, frustration between parties will be lessened and the quality of HIV testing will increase.

Remember, we all share a common goal.

Specimen Collection & Testing

Phlebotomy on-site
At all times that rapid testing occurs at [Site], someone must be on-site who is legally able to perform fingersticks and blood draws in the State of California. [Include information here about who this will be for your site. Is it a nurse or doctor who is readily available? Is it a CA state-certified phlebotomist who will be scheduled for each rapid testing shift? etc.]

Laboratory Specifications
[Include information here about your site-specific procedures for collecting the specimen and running the rapid test. Will counselors also certified as test technicians collect the OraQuick sample from the client in the counseling room. Does walk it to the lab area? Or will they walk the client to the lab area to collect the sample and run the test? Will you have separate staff members providing counseling from those collecting the specimen and running the OraQuick test in the lab room (this is required for Stat-Pak and Lipo-Gold specimens)? Also, what supplies will be maintained in the laboratory area (goggles, bench protectors, sharps containers, etc.)? How will the area be secured from unauthorized entry, and how will client confidentiality be maintained? Where will confirmatory blood draws take place? Will this be done by a qualified counselor, or will it be a different staff person entirely? Provide any other site-specific details here about the laboratory setup.]

Universal Precautions will be followed at all times in the laboratory area and during specimen collection. For purposes of rapid testing, use of universal precautions includes:
 1. All specimens and material containing specimens must be handled as if they are capable of transmitting an infectious organism. This includes control vials, and all rapid test kits, even if used only with oral specimens.
 2. During testing, certified technicians must use protective equipment such as gloves and lab coats.
 3. All certified technicians must follow procedures for biohazard safety such as hand washing, use of gloves, sharps and biohazardous waste disposal, and spill containment and disinfection.

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Facente Consulting is a small consulting firm that specializes in HIV testing and HIV prevention program development. Drawing upon years of experience providing technical assistance to community-based organizations in the San Francisco Bay Area and beyond, Facente Consulting is well-situated to help any entity—government, community-based, or corporate—to strengthen or successfully expand their HIV programs.