

# Rapid HIV Testing

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## Overview

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Early diagnosis of acute human immunodeficiency virus (HIV) infection via rapid HIV testing can identify patients who will benefit from antiretroviral treatment, which has been shown to delay the progression to acquired immunodeficiency syndrome (AIDS) and death<sup>[1]</sup> and to reduce the transmission of HIV. Rapid HIV testing may also be useful to quickly confirm the diagnosis of HIV infection in patients who present with an AIDS-defining illness but have unknown HIV status.

The Centers for Disease Control and Prevention (CDC) recommends universal HIV screening of all US residents aged 13-64 years and annual screening for high-risk populations.<sup>[2]</sup> The US Preventive Services Task Force recommends screening for ages 15-65 years and for those outside this range with HIV risk factors.<sup>[3]</sup> This can be completed at any convenient healthcare encounter, including primary care, urgent care, emergency department visits, outreach programs utilizing mobile clinics or kiosks, or even in patients' homes.

Studies have shown that nearly one third of patients screened for HIV by traditional programs with pretest counseling and blood tests that are sent to a central laboratory fail to return for follow-up visits to learn the results.<sup>[4]</sup> Rapid HIV testing has the benefit of allowing counselling and results during a single encounter. Identification of asymptomatic HIV-positive patients benefits the individual and the public health. Seropositive patients can be referred for treatment and taught about practices that will help reduce the risk of infecting others.<sup>[5]</sup>

For other discussions on HIV infection, see HIV Disease, Pediatric HIV Infection, and Antiretroviral Therapy for HIV Infection, as well as HIV in Pregnancy.

## Patient Education

Provide frank, complete, nonjudgmental information on the routes of transmission. Teach HIV-infected patients how to minimize the risk to others.

For patient education information, see the Sexual Health Center, Rapid HIV Test, and HIV/AIDS.

For more information, see the CDC guidelines for HIV Infection: detection, counseling, and referral and revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings.

## Pretest and Posttest Counseling

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Pretest and posttest counseling can be done by nonmedical personnel. Pretest counseling can be completed in person, via prerecorded video, or pamphlet and takes less than 20 minutes. Counseling protocols and counselor prompt cards are available on the CDC website. A system for posttest referrals needs to be prearranged for patients with positive rapid test results to facilitate follow-up.

If HIV seropositivity is expected, patients whose test results are positive with rapid HIV tests should be told they likely have HIV and need further confirmatory testing. If HIV is not likely, a patient with a positive rapid test result should be counseled that he or she may have HIV but that a confirmatory test is necessary. Patients are expected to be anxious after learning rapid HIV test results.

Patients with a high suspicion for acute HIV infection and a probable false-negative rapid HIV test result should have HIV RNA viral load testing done and should be referred for follow-up HIV ELISA testing. Remember that during acute HIV infection, the antibody test ELISA, will usually be negative.

Protect patient confidentiality. Patients may not have informed family members or friends of their risk behaviors or diagnosis.

## Test Settings

Outreach programs can provide rapid HIV testing in the community. Counseling and testing can be completed anywhere, including in patients' homes. These programs provide an opportunity to identify high-risk patients who otherwise would not seek outpatient testing. Emergency department (ED) testing has the following features:

- Routine HIV screening of asymptomatic patients and outpatient referral for confirmatory testing and care (routine opt-out screening of ED patients may result in increased numbers of patients tested and identified as HIV positive compared to physician-directed screening <sup>[6]</sup>)
- Identification of acute HIV infection with possible ED diagnosis and/or referral for further diagnostics and treatment
- Confirmation of diagnosis of HIV in patients with AIDS-defining illness, previously not known to be seropositive
- There are multiple models of HIV screening in the ED. "Opt out" programs, as recommended by the CDC, have the potential to screen the greatest number of patients compared to "opt in" programs, but may be hindered by state laws governing consent to testing and refusal of testing and burden the ED with increased costs of testing. <sup>[7]</sup> Having a dedicated counselor screen for HIV has been shown to be significantly more successful than provider-based screening; however, there is an added cost to a counselor-based testing program. <sup>[8]</sup> Replacing counselors with trained ED technicians has been shown to increase rates of testing. <sup>[9]</sup> In addition, some sites have found success with novel self-testing kiosks. <sup>[10]</sup>

## Follow-up

HIV-positive patients should be referred for confirmatory testing and further outpatient treatment as needed. If acute HIV infection is suspected, send a specimen for HIV RNA viral load testing or recommend a repeat HIV test in 4-8 weeks.

Do not discharge patients with newly diagnosed HIV infection without proper follow-up for testing or treatment. Make sure follow-up care has been arranged for patients prior to initiating an HIV screening program.

## Table: FDA-Approved Rapid HIV Tests

The US Food and Drug Administration (FDA) has approved a number of Clinical Laboratory Improvement Amendment (CLIA)-waived rapid HIV tests (see Table 1).<sup>[11]</sup> These tests assess for HIV antibodies with an enzyme-linked immunosorbent assay (ELISA). Sensitivity and specificity are greater than 99%. Results are reported as reactive or nonreactive.

The FDA-approved kits have been shown to perform similarly,<sup>[12]</sup> with the exception of the Determine HIV test, which is a fourth-generation test that also detects p24 antigen, increasing the ability to detect very early infection.

Table 1. FDA-Approved CLIA-Waived Rapid HIV Tests ([Open Table in a new window](#))

TestName	Specimen Needed	Turnaround Time (minutes)	Median Days from Infection to Detection**

OraQuick Advance	Oral swab or blood (fingerstick or venipuncture)	20	34
Uni-Gold Recombigen	Whole blood (fingerstick or venipuncture)	10	32
Chembio Sure Check	Whole blood (fingerstick or venipuncture)	15	30
INSTI HIV	Fingerstick whole blood	< 2	24
Determine HIV	Whole blood (fingerstick or venipuncture)	20	17
Chembio DPP	Fingerstick whole blood	15	28
Clearview Stat Pak	Fingerstick or venous whole blood	15	***

\*CLIA (Clinical Laboratory Improvement Amendment) "waived" means testing does not have to be done by certified laboratory staff.

\*\* Median days to detect infection is based on the estimated days from first infection that the test first detects the HIV infection, which includes the approximately 10-day period from initial infection to detection of HIV-1 RNA.

\*\*\*No data, as Clearview Stat Pak was not included in the referenced study.

Note: If the rapid test is reactive, confirm the result with Western blot or immunofluorescent assay (IFA). Western blot results are reported as positive, negative, or indeterminate. Indeterminate tests result from nonspecific reactions of HIV-negative sera with some HIV proteins. If the result is indeterminate, repeat the ELISA test in 1 month.

Nonreactive tests in patients with a strong likelihood of acute HIV infection should be followed up with a virologic test such as HIV RNA assay (viral load). Viral load is very high (>100,000 copies/mL) in acute HIV infection. If virologic test is positive, repeat antibody testing in 3 months after seroconversion.

False-positive and false-negative tests do occur with rapid testing. Positive predictive value is lower in populations with low HIV prevalence, so there will be relatively more false-positive tests in these groups with very low HIV risk factors.

## Questions & Answers

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### Overview

What is rapid HIV testing?

What is included in patient education about rapid HIV testing?

What is included in pretest and posttest counseling for rapid HIV testing?

When is emergency department (ED) rapid HIV testing performed?

What is included in the follow-up in patients with a positive rapid HIV testing result?

What are the FDA-approved rapid HIV tests?

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