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Screening Adults for HIV Using Point-of-service Tests

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Rapid point-of-service (POS) HIV tests are becoming powerful screening tools in a multitude of clinical settings. As these tests become more accessible and easier to implement, they will likely be used more frequently by primary care practitioners, including nurse practitioners. This article discusses the emergence of POS HIV screening, the most recent Centers for Disease Control and Prevention (CDC) recommendations regarding HIV screening in adults, the types of POS HIV screening methods that are available, protocols for confirming positive test results, billing and insurance considerations, and limitations of POS HIV screening.



Emergence of Point-of-service HIV Screening

Forty-four percent of HIV-positive patients enter the healthcare system after routine screening.^{1,3} Early screening can lead to faster diagnosis and treatment, resulting in reduced mortality; therefore, early HIV detection is essential.^{1,3} Patients at greatest risk for HIV exposure and infection may not be

screened as often as necessary.¹ According to a 2007 report, <25% of moderate- to high-risk individuals were screened for HIV in the previous year.⁴ In 2003, the CDC estimated that 25% of HIV-positive individuals in the United States were unaware of their infective serostatus.^{5,6} As a consequence, that same year, the CDC launched its Advancing HIV Prevention initiative, designed to promote increased

HIV screening of high-risk individuals and earlier initiation of treatment for those found to be infected. A cornerstone of this effort was the use of rapid POS HIV antibody screening.^{5,6} These screening tests assess for the presence of HIV antibodies in saliva or whole blood; results are available and evaluable by a healthcare practitioner *during the same visit*.⁷ Clinical trials of POS HIV screening show that the tests have an overall accuracy rate of 99.6%.⁸

Although POS HIV antibody screening tests may not be widely used by NPs in primary care settings, research suggests these tests, compared with the standard enzyme-linked immunosorbent assay (ELISA) HIV screening test, can identify a greater number of persons at high risk who are unaware of their HIV infection.⁵ (Recent estimates are that 252,000-312,000 persons in this country are unaware of their HIV seropositivity.¹) One of the greatest advantages of POS HIV testing is its provision of an opportunity not only to screen patients for HIV, but also to educate them regarding risk factors, discuss the screening test results with them, and ensure that they know their serostatus—all *within one clinical visit*.

Compared with the time period needed to learn patients' HIV serostatus using ELISA-Western blot screening (days to weeks, depending on the testing agency and a patient's compliance in terms of returning to the office or clinic to learn the results), POS testing affords notification of HIV status within 20 minutes. The CDC reported that 31% of patients receiving standard testing—that is, blood screening through ELISA and confirmation through Western blot in publicly funded testing

TABLE 1 MAJOR REVISIONS IN CDC GUIDELINES IN HIV SCREENING¹

- HIV screening is recommended for patients in all healthcare settings after patients are notified that testing will be performed. Patients have the option to decline testing.
- Persons at high risk for HIV infection should be screened at least annually.
- Separate written consent for HIV testing should not be required; general consent for health care should be considered sufficient to encompass consent for HIV testing.
- Prevention counseling should not be required with HIV diagnostic testing or as part of HIV screening programs in healthcare settings.

CDC, Centers for Disease Control and Prevention; HIV, human immunodeficiency virus.

sites—did not return for their results.⁷ By contrast, one study showed that 100% of patients who opted for POS HIV testing obtained their results (because the results are available so rapidly).⁹

CDC Recommendations for HIV Screening in Adults

In its *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings*, published in 2007, the CDC made major revisions to its previous guidelines in order to increase HIV screening rates (Table 1).^{1,5} Although several activities have been identified as being potentially high-risk for HIV transmission, patients generally considered to be at highest risk are those who have unprotected sex and those who are injection drug users.¹⁰ In particular, the CDC recommends annual screening for patients who (1) inject drugs or steroids with previously-used injection equipment; (2) have sex for money or drugs; (3) have sex with an HIV-infected person; (4) have had more than one sex partner since the previous HIV screening; and (5) have had a sex partner

who has had other sex partners since the previous HIV screening.¹¹

In addition, the CDC recommends immediate HIV screening in any person seeking treatment for tuberculosis or a sexually transmitted infection.¹ Consent for HIV screening can be incorporated into general consent for treatment; the CDC no longer recommends a separate consent document for HIV testing.¹ Although prevention counseling is no longer required, the CDC strongly encourages it for high-risk persons during routine assessments.¹ Patients may opt out of HIV screening at any time, but NPs need to discuss and document patients' reasons for declining the test. NPs should emphasize the need for an HIV test despite a previous negative test result and ascertain any logistical reasons that may be discouraging patients from being tested.¹

Approved POS HIV Screening Tests

Since November 2002, the US Food and Drug Administration (FDA) has approved four different rapid HIV screening tests that can be done at the POS because these

tests use whole blood or oral fluids and are simple to perform.⁷ These tests include the OraQuick Advance Rapid HIV-1/2 Antibody Test, Uni-Gold Recombigen HIV test, HIV 1/2 Stat-Pak Assay, and the Sure Check HIV 1/2 Assay (Table 2).⁷

■ The OraQuick Advanced Rapid HIV-1/2 Antibody Test can be used with oral fluid or finger stick/venipuncture specimens, collected with a 5- μ L loop. If oral fluid is used, the upper and lower gums are swabbed with the device. After the specimen is collected, it is placed in a vial of developer solution along with the 5- μ L collection loop. Tests results are read 20-40 minutes later. A negative test result is indicated by the presence of one red line in the indicator, whereas seropositivity is indicated by two red lines appearing in the indicator. If no lines appear, the sample was inadequate and should be repeated.⁷

■ The Uni-Gold Recombigen HIV test screens for HIV-1 using whole blood obtained from a finger stick or venipuncture. A 40- μ L drop of blood, serum, or plasma is collected on the test device along with 4 drops of buffer solution. Results are read in 10 minutes. A single red line indicates a negative test result, whereas two red lines indicate a positive test result. Absence of lines means the test is invalid and should be repeated.⁷

■ The HIV 1/2 Stat-Pak Assay uses whole blood obtained by finger stick or venipuncture. The specimen is obtained with a 5- μ L loop and applied to the sample well of the test cartridge with 3 drops of buffer. Results are analyzed in 15-20 minutes. As with the other tests discussed, one line is consistent with a negative test result and two lines indicate seropositivity.⁷

■ The Sure Check HIV 1/2 Assay detects HIV-1 and HIV-2 antibodies using a whole blood sample collected from a finger stick

or a venipuncture. The device, similar in appearance to the barrel of a syringe, houses a test strip used to collect a 2.5- μ L sample that is placed into a vial of developer solution. Results are available in 15-20 minutes; one red line indicates a negative test result and two red lines indicate a positive test result.⁷

Protocols for Confirmation of Positive POS HIV Screening Tests

POS HIV screening tests have sensitivities and specificities similar to those of conventional enzyme immunoassay (EIA) screening tests.¹² Negative results do not need to be confirmed through secondary analysis.⁷ However, the CDC has specific protocols for confirmation of positive POS HIV screening test findings. In particular, any reactive POS HIV screening test should be confirmed using the Western blot (also used to verify a positive ELISA screening test

TABLE 2 POINT-OF-SERVICE HIV SCREENING TESTS⁷

Test	Type of Sample	Amount of Sample	Time for Determination of Results	Negative Result	Positive Result
OraQuick Advanced Rapid HIV 1/2 Antibody Test	Oral fluid or finger stick/venipuncture specimen	5- μ L	20-40 minutes	One line on indicator	Two lines on indicator
Uni-Gold Recombigen HIV Test	Whole blood obtained from finger stick/venipuncture	40- μ L	10 minutes	One line on indicator	Two lines on indicator
HIV 1/2 Stat-Pak Assay	Whole blood obtained from finger stick/venipuncture	5- μ L	15-20 minutes	One line on indicator	Two lines on indicator
Sure Check HIV 1/2 Assay	Whole blood obtained from finger stick/venipuncture	2.5- μ L	15-20 minutes	One line on indicator	Two lines on indicator

HIV, human immunodeficiency virus.

TABLE 3 POS HIV SCREENING-ASSOCIATED CPT CODES¹⁶

Code	Rapid Test Modifier/Notes	Description
86701	92	Antibody; HIV-1
86702	92	Antibody; HIV-2
86703	92	Antibody, HIV-1 and HIV-2, single assay
87390	N/A	Enzyme immunoassay, HIV-1
86689	N/A	HIV antibody confirmatory test (eg, Western blot)
99385	N/A	Initial preventive office visit (new patients aged 18-39 y)
99386	N/A	Initial preventive office visit (new patients aged 40-64 y)
99395	N/A	Periodic preventive office visit (established patients aged 18-39 y)
99386	N/A	Periodic preventive office visit (established patients aged 40-64 y)
99211	N/A	HIV counseling for patients with positive test results
V73.89	Used in addition to routine examination	Patients seen to determine HIV status
V69.8	Used in addition to routine examination	Asymptomatic patients considered at high risk for HIV infection
V65.44	Added as additional code (if applicable)	HIV counseling/education provided during visit

CPT, Current Procedural Terminology; HIV, human immunodeficiency virus; N/A, not available; POS, point-of-service.

result) or immunofluorescent assay (IFA).^{7,13} CDC guidelines specifically recommend confirmation through these methods, even if a traditional EIA test (eg, the traditional ELISA HIV antibody screening test) yields a negative finding in patients with a positive POS HIV screening test result.

NPs may confirm a positive POS HIV screening test result by ordering the Western blot test (ordering the traditional ELISA HIV antibody screening test is unnecessary). In addition, the CDC recommends that patients with a positive POS HIV screening test result but a negative confirmation test result be retested after 1 month to rule out specimen mix-up or early infection not yet detectable via Western blot.¹³ Finally, NPs must remember that the window period for appearance

of HIV antibodies can be up to 3 months; persons with possible recent exposure to HIV through high-risk activity are retested within 3 months.⁷

Billing and Insurance Implications of POS HIV Screening Tests

Because POS HIV screening tests are considered laboratory analyses, clinics using them must maintain Clinical Laboratory Improvement Amendments (CLIA) standards and regulations and meet state-specific requirements.¹⁴ Organizations can apply for their own CLIA certificate; information related to the application for a CLIA certificate is found on the Centers for Medicare and Medicaid Services website (http://www.cms.hhs.gov/clia/01_overview.asp?).¹⁵

Effective since January 1, 2008, NPs can bill for performing HIV

screening with a rapid test kit.¹⁶ Modifier “92” can be added for “Alternative Laboratory Platform Testing” to the usual laboratory procedure code for HIV testing within the *Current Procedural Terminology (CPT)* system.¹⁶ Table 3 lists other CPT codes that are appropriate for a primary care clinic visit incorporating POS HIV screening tests.

Limitations of POS HIV Screening Tests

Like most diagnostic and screening tests, the POS HIV screening tests have limitations. NPs using POS HIV screening in clinical practice must maintain quality assurance.⁷ The availability of nearly immediate test results necessitates that NPs help HIV-infected persons comprehend their illness and actively engage in the healthcare system.⁷

NPs may confirm a positive POS HIV screening test result by ordering the Western blot test.

POS HIV screening tests are powerful tools in that they can facilitate earlier entry of newly diagnosed HIV-infected persons into the healthcare system.² Sound clinical judgment and a therapeutic NP-patient relationship are essential to successful screening, accurate diagnosis, and effective follow-up.⁷

NPs must understand the need for confirmatory testing when appropriate, and they should be knowledgeable about HIV evaluation and treatment in order to answer patients' questions regarding the diagnostic and post-diagnostic processes. Although POS HIV screening tests represent a major advancement in HIV screening, they can have unintended consequences.¹⁷ Although HIV cannot be transmitted or contracted through saliva, a study by Clair et al¹⁷ found an increased belief that HIV could be spread through saliva among patients being tested with a POS HIV screening test sampling saliva. NPs using POS HIV screening tests in their practice must provide appropriate education and counseling to patients undergoing screening.¹⁷

Conclusion

POS HIV screening tests are emerging tools with great clinical relevance for NPs working in primary care settings. To properly use these screening tests in clinical practice, NPs should have first-hand knowl-

edge of the most recent CDC guidelines for HIV screening in adults, the types of POS HIV screening methods that are FDA-approved, protocols for confirmation of positive test results, billing and insurance implications, and limitations of POS HIV screening.

When used correctly, POS HIV tests can facilitate greater screening of high-risk persons and provide a means for rapid screening of HIV antibodies in blood or saliva. NP can screen, counsel, and educate patients, and provide diagnostic results during a single visit. Among HIV-infected persons, research supports use of HIV POS screening tests to facilitate quicker access into the healthcare system for earlier evaluation and treatment, resulting in more favorable clinical outcomes and lower morbidity and mortality.^{2,3,17} ■

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