



DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
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UNDER SECRETARY FOR HEALTH'S INFORMATION LETTER

**USE OF RAPID TESTS FOR ROUTINE HUMAN IMMUNODEFICIENCY
VIRUS (HIV) SCREENING**

1. Purpose. This Information Letter (IL) provides the current scientific evidence and recommendations for the use of rapid tests for routine screening for HIV infection; in particular it provides information regarding the performance characteristics of these tests relative to traditional HIV tests in order to assist clinicians and facility Laboratory Directors considering implementation of rapid HIV tests on a point-of-care basis. This IL also provides information to assist clinicians and Laboratory Directors on compliance with applicable Federal and Department of Veterans Affairs (VA) laboratory regulatory standards.

2. Background

a. In 2006, the United States (U.S.) Centers for Disease Control and Prevention (CDC) recommended voluntary HIV testing of patients in all health care settings unless the diagnostic yield is less than 0.1 percent (see subpar. 4a). Despite ongoing HIV prevention and education efforts, it is estimated that 21 percent of those with HIV infection in the United States are unaware of their status (see subpar 4b). Undiagnosed HIV infection is also a problem in the Veterans Health Administration (VHA), with the prevalence of undiagnosed infection at six large VA sites ranging from 0.1 percent to 2.8 percent among outpatients (see subpar. 4c). In accordance with the 2006 CDC recommendations, on August 17, 2009, VHA changed its policy on HIV testing from "risk-based" screening to routine voluntary HIV testing of all Veterans as a part of routine medical care (see subpar. 4d).

b. Rapid HIV tests have been used nationally in clinical and non-clinical health care settings with accuracy and ease and to help expand access and availability of HIV testing (see subpar. 4e). Furthermore, rapid tests have benefited patients by simplifying the results notification process and ensuring opportunities for timely linkage to care.

c. There are currently six rapid HIV tests approved by the U.S. Food and Drug Administration (FDA) (see Att. A). Reactive rapid HIV tests are considered preliminary positives and need to be confirmed with a conventional Western Blot or immunofluorescent assay performed on serum (see subpar. 4f). Similar sensitivities [99.3-100 percent] and specificities [98.6-99.9 percent] have been reported for all rapid HIV tests, regardless of specimen source used. The performance characteristics of these tests are comparable to traditional HIV Enzyme-Linked Immunosorbent Assay (ELISA) testing. The only rapid HIV

test approved by FDA for use on oral fluid is the OraQuick Advance Rapid HIV. The five other FDA-approved rapid HIV tests must be performed on whole blood (obtained by venipuncture or finger-stick), serum or plasma and are not conducted on oral fluid.

d. There are limitations to the use of rapid HIV tests. Clusters of false positive oral fluid tests have been reported (see subpar. 4g). As with all screening tests, lower positive predictive values are seen in areas of low prevalence. However, the negative predictive value of these tests has remained consistently greater than 99.9 percent throughout studies and reports regardless of the prevalence of infection in the community. Reactive rapid screening tests are considered preliminary positive results and need to be confirmed with a HIV Western blot or immunofluorescent assay performed on serum (see subpar. 4f).

e. These tests fall into various categories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88): waived, moderate complexity, or high complexity (see Att. A). Use of these tests on a point-of-care basis requires training of personnel performing and interpreting the test, documentation of training and of quality control procedures and results, proficiency testing, and appropriate storage of training and quality control records, as well as appropriate procedures for reporting results into the Computerized Patient Record System. Point-of-care testing needs to be supervised and approved by facility Laboratory Directors.

3. Recommendations

a. FDA-approved rapid HIV tests have produced accurate and reliable results in multiple clinical and non-clinical settings. In high prevalence areas, rapid HIV tests may be useful to implement VHA Directive 2009-036 to increase the number of Veterans tested for HIV as part of routine medical care, facilitate notification of Veterans of test results, and help with timely linkage to care.

b. A number of VHA facilities have successfully implemented rapid HIV testing as part of efforts to expand HIV testing. Successful implementation efforts have involved a clinical champion (e.g., HIV Lead Clinician, HIV Care Coordinator, or a Primary Care provider) working closely with the facility Laboratory Director, as well as other stakeholders, such as the Nursing Service. All health care providers, including nurses, can perform a rapid HIV test as long as they are authorized to do so under their local facility scope of practice, have received appropriate documented training, and meet other applicable regulatory requirements as determined by the facility Laboratory Director. Details of successful efforts to institute point-of-care or laboratory-based rapid HIV testing can be obtained from the Public Health Strategic Health Care Group at publichealth@va.gov.

c. Providers and Laboratory Directors need to be aware of the limitations of reactive rapid HIV screening tests and the need for confirmation in accordance with current guidelines. Negative predictive values are greater than 99.9 percent and, therefore, providers can have confidence that a negative rapid test result, in the absence of a recent exposure to HIV, is conclusive.

d. Failure to implement and follow appropriate Federal and VHA regulations regarding point-of-care laboratory testing can jeopardize patient safety and may result in sanctions on VA facilities. Therefore, HIV Lead Clinicians and other individuals involved with HIV testing need to work closely with Laboratory Directors prior to the implementation of any rapid HIV testing program. Under VHA Directive 2009-036, Laboratory Directors are responsible for compliance with Federal and VA policies with respect to CLIA-88 and VHA Handbook 1106.01; therefore, clinical providers performing point-of-care HIV testing need to comply with applicable policies put forth by the Laboratory Director.

4. **References**

a. CDC. “Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings.” Morbidity and Mortality Weekly (MMWR) 2006;55 (RR14):1-17.

b. CDC. “HIV Prevalence Estimates -- United States, 2006.” MMWR 2008;57 (39) 1073 – 1076.

c. Owens DK, *et al.*, “Prevalence of HIV Infection among Inpatients and Outpatients in Department of Veterans Affairs Health Care Systems: Implications for Screening Programs for HIV”. American Journal of Public Health. 2007: 97(12):2173-8..

d. VHA Directive 2009-036: Testing for Human Immunodeficiency Virus in Veterans Health Administration Facilities.

e. Delany KP, *et al.* “Performance of an oral fluid rapid HIV-1/2 test: experience from four CDC studies.” AIDS 2006, 20(12):1655-1660.

f. CDC. “Notice to Readers: Protocols for Confirmation of Reactive Rapid HIV Tests.” MMWR 2004; 53(10): 221-2.

g. CDC. “False-Positive Oral Fluid Rapid HIV Tests --- New York City, 2005—2008.” MMWR 2008;57:1-5.

5. **Inquiries.** The Public Health Strategic Health Care Group (13B) is responsible for the contents of this IL. Questions may be addressed to the Director, National Clinical Public Health Programs at publichealth@va.gov or (202) 461-1040.

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ATTACHMENT A

FOOD AND DRUG ADMINISTRATION (FDA)-APPROVED RAPID HUMAN
IMMUNODEFICIENCY VIRUS (HIV) ANTIBODY SCREENING TESTS

	Manufacturer	FDA-Approval Received	Specimen Type	CLIA-88* Category	Sensitivity Percent (95 percent CI)	Specificity Percent (95 percent CI)
OraQuick ADVANCE Rapid HIV-1/2 Antibody Test	OraSure Technologies, Inc.	June 2004	Oral fluid	Waived	99.3 (98.4-99.7)	99.8 (99.6-99.9)
Uni-Gold Recombigen HIV	Trinity Biotech	Dec 2003	Whole blood (fingerstick or veni-puncture)	Waived	100 (99.5-100)	99.7 (99.0-100)
			Serum and Plasma	Moderate Complexity	100 (99.5-100)	99.8 (99.3-100)
Reveal G-3 Rapid HIV-1 Antibody Test	MedMira, Inc.	Apr 2003	Serum	Moderate Complexity	99.8 (99.2-100)	99.1 (98.8-99.4)
			Plasma	Moderate Complexity	99.8 (99.0-100)	98.6 (98.4-98.8)
MultiSpot HIV-1/HIV-2 Rapid Test	BioRad Laboratories	Nov 2004	Serum	Moderate Complexity	100 (99.94-100)	99.93 (99.79-100)
			Plasma	Moderate Complexity	100 (99.94-100)	99.91 (99.77-100)
Clearview HIV 1/2 STAT-PAK	Inverness Medical Professional Diagnostics	May 2006	Whole Blood (finger stick or veni-puncture)	Waived	99.7 (98.9-100)	99.9 (99.6-100)
			Serum and Plasma	Non-waived	99.7 (98.9-100)	99.9 (99.6-100)
Clearview COMPLETE HIV 1/2	Inverness Medical Professional Diagnostics	May 2006	Whole Blood (finger stick or veni-puncture)	Waived	99.7 (98.9-100)	99.9 (99.6-100)

*CLIA - Clinical Laboratory Improvement Amendments of 1988

Adapted Content Source from: Divisions of HIV/AIDS Prevention; National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention; at www.cdc.gov