Rapid Test

Rapid tests for HIV are assays that detect antibodies to HIV within minutes. Many of these tests use easily collected fingerstick blood and oral fluid samples and have one-step procedures that are reliable for screening. Some require little training to perform and interpret; a positive result is indicated by the presence of a pink line or circle in the appropriate area. The specific tests that have been approved, the indications for use, and the manner in which they are used are evolving. Table 2 lists the characteristics of each of the current FDA-approved rapid tests. Additional information is also available on the Food and Drug Administration (FDA) website.

All of the rapid tests detect antibody to HIV and thus will not detect very recent infection with any more accuracy than the standard HIV antibody tests. All have sensitivity and specificity similar to standard HIV antibody tests and similar positive and negative predictive values. They were tested with specimens from patients with potentially interfering substances, including anti-nuclear antibody, C-reactive protein, infectious mononucleosis, and antibodies to HCV, EBV, CMV, HSV, rubella, rheumatoid arthritis, varicella, HAV, HBV, HCV, syphilis, mycoplasma, and streptolysin-O. Samples from patients receiving anticoagulants and from those who had chemical derangements of the blood also had predictive values similar to those from normal samples.

In New York State, a rapid test is defined as an HIV screening test that produces results within 60 minutes or less. Rapid testing is the method of choice when immediate information is necessary to determine the need for prophylaxis, such as in the labor/delivery, newborn, or post-exposure settings, or when the person who is being tested is unlikely to return for a follow-up visit.

When rapid testing is performed, preliminary positive test results should be given to the patient before confirmatory test results are available. Confirmatory WB testing of preliminary positive test results should be completed as soon as possible. Specific protocols and test methods are outlined in Section II. A. 2: *HIV-1 Confirmatory Antibody Assays*.

Each of the rapid tests is restricted to the body fluid(s) it was designed to analyze (see Table 2). A "waived" test means that the FDA has established that it can be performed by persons with limited training under the auspices of a clinical laboratory (see the FDA's CLIA Certificate of Waiver Fact Sheet for more information), whereas a test without a waiver is characterized as being a nonwaived test of "moderate complexity" and must be performed by only certified personnel at a licensed laboratory (see Table 2). When issuing certificates for nonwaived tests, the New York State Department of Health inspects testing facilities and personnel for compliance with the federally mandated Clinical Laboratory Improvement Amendments (CLIA).

Table 2: Characteristics of FDA-Approved Rapid HIV Tests							
FDA-Approved Rapid HIV Tests							
Characteristic	**OraQuick Advance Rapid HIV-1/2**	**Reveal G3 Rapid HIV-1**	**Multispot HIV-1/HIV-2**	**Uni-Gold Recombigen HIV**	**Clearview HIV 1/2 Stat-Pak**	**Clearview Complete HIV 1/2**	**INSTI HIV-1 Antibody Test**
Manufacturer	OraSure Technologies	MedMira, Inc.	Bio-Rad Laboratories	Trinity Biotech	Inverness Medical	Inverness Medical	bioLytical Laboratories
Detection	HIV-1 and -2	HIV-1	HIV-1 and -2	HIV-1	HIV-1 and -2	HIV-1 and -2	HIV-1
Specimen	Oral fluid, whole blood, plasma	Serum, plasma	Serum, plasma	Whole blood, serum, plasma	Whole blood, serum, plasma	Whole blood, serum, plasma	Whole blood, plasma
Sensitivity[a] (95%)	99.3% (oral fluid); 99.6% (whole blood[b]); 99.6% (plasma)	99.8%	100%	100% (whole blood[b]); 100% (serum, plasma)	99.7% (whole blood[b]); 99.7% (serum, plasma)	99.7% (whole blood[b]); 99.7% (serum, plasma)	99.8% (fingerstick whole blood); 99.9% (venipuncture whole blood); 99.9% (plasma)
Specificity (95%)	99.8% (oral fluid); 100% (whole blood[b]); 99.9% (plasma)	99.1% (serum); 98.6% (plasma)	99.93%	99.7% (whole blood[b]); 99.8% (serum, plasma)	99.9% (whole blood[b]); 99.9% (serum, plasma)	99.9% (whole blood[b]); 99.9% (serum, plasma)	99.5% (fingerstick whole blood); 100% (venipuncture whole blood); 100% (plasma)
CLIA category[c]	Waived: oral fluid and whole blood[b] only	Moderate Complexity: No waiver	Moderate Complexity: No waiver	Waived: whole blood[b] only	Waived: whole blood[b] only	Waived: whole blood[b] only	Moderate Complexity: No waiver

CLIA, Clinical Laboratory Improvement Amendments.
[a]Data shown are for HIV-1 only. For HIV-2 data, see package inserts.
[b]Fingerstick and venipuncture.
[c]Information regarding CLIA waivers of HIV tests is available at: www.cdc.gov/hiv/topics/testing/resources/factsheets/roltCLIA.htm. Information about or assistance with completing the CLIA waiver application can be obtained by calling Centers for Medicare & Medicaid Services toll-free at: 1-877-267-2323.