

## FDA-Approved Rapid HIV Antibody Screening Tests

February 4, 2008

	<b>FDA Approval Received</b>	<b>Specimen Type</b>	<b>CLIA Category*</b>	<b>Sensitivity** (95% CI)</b>	<b>Specificity** (95% CI)</b>	<b>Manufacturer</b>	<b>Approved for HIV-2 Detection?</b>	<b>List Price Per Device<sup>^</sup></b>	<b>External Controls</b>
<b>OraQuick ADVANCE Rapid HIV-1/2 Antibody Test</b>	Nov 2002	Oral fluid	Waived	99.3% (98.4-99.7)	99.8% (99.6-99.9)	OraSure Technologies, Inc. <a href="http://www.orasure.com">www.orasure.com</a>	Yes	\$17.50	Sold Separately (\$25 each)
		Whole Blood (finger stick or venipuncture)	Waived	99.6% (98.5-99.9)	100% (99.7-100)				
		Plasma	Moderate Complexity	99.6% (98.9-99.8)	99.9% (99.6-99.9)				
<b>Uni-Gold Recombigen HIV</b>	Dec 2003	Whole blood (fingerstick or venipuncture)	Waived	100% (99.5-100)	99.7% (99.0-100)	Trinity Biotech <a href="http://www.unigoldhiv.com">www.unigoldhiv.com</a>	No	\$15.75  \$8.00*	Sold Separately (\$26.25 each)
		Serum & Plasma	Moderate Complexity	100% (99.5-100)	99.8% (99.3-100)				
<b>Reveal G-3 Rapid HIV-1 Antibody Test</b>	Apr 2003	Serum	Moderate Complexity	99.8% (99.2-100)	99.1% (98.8-99.4)	MedMira, Inc. <a href="http://www.medmira.com">www.medmira.com</a>	No	\$14.00	Included
		Plasma	Moderate Complexity	99.8% (99.0-100)	98.6% (98.4-98.8)				

▪ "Public health" price for public health programs that are recipients of CDC funds for expanded HIV testing

\* Clinical Laboratory Improvement Amendments: CLIA regulations identify three categories of tests: waived, moderate complexity, or high complexity

\*\* Sensitivity is the probability that the test result will be reactive if the specimen is a true positive; specificity if the probability that the test result will be nonreactive if the specimen is a true negative. Data are from the FDA summary basis of approval, for HIV-1 only. For HIV-2 information, see package inserts.

<sup>^</sup> Actual price may vary by purchasing agreements with manufacturers

Note: Trade names are for identification purposes only and do not imply endorsement. This information was compiled from package inserts and direct calls to manufacturers.

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<b>MultiSpot HIV-1/HIV-2 Rapid Test</b>	Nov 2004	Serum	Moderate Complexity	100% (99.94-100)	99.93% (99.79-100)	BioRad Laboratories <a href="http://www.biorad.com">www.biorad.com</a>	Yes – differentiates HIV-1 from HIV-2	\$25.00	Included
		Plasma	Moderate Complexity	100% (99.94-100)	99.91% (99.77-100)				
<b>Clearview HIV 1/2 STAT-PAK</b>	May 2006	Whole Blood (finger stick or venipuncture)	Waived	99.7% (98.9-100)	99.9% (99.6-100)	Inverness Medical Professional Diagnostics <a href="http://www.invernessmedicalpd.com">www.invernessmedicalpd.com</a>	Yes	\$17.50 \$8.00*	Sold Separately (\$50/set)
		Serum & Plasma	Non-waived	99.7% (98.9-100)	99.9% (99.6-100)				
<b>Clearview COMPLETE HIV 1/2</b>	May 2006	Whole Blood (finger stick or venipuncture)	Waived	99.7% (98.9-100)	99.90% (99.6-100)	Inverness Medical Professional Diagnostics <a href="http://www.invernessmedicalpd.com">www.invernessmedicalpd.com</a>	Yes	\$18.50 \$9.00*	Sold Separately (\$50/set)
		Serum & Plasma	Non-waived	99.7% (98.9-100)	99.9% (99.6-100)				

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