

# RAPID HIV TESTS SUITABLE FOR USE IN NON-CLINICAL SETTINGS (CLIA-WAIVED<sup>1</sup>)

Updated July 2015

Brand		<a href="#">OraQuick Advance HIV 1/2 Antibody Test</a>	<a href="#">Uni-Gold Recombigen HIV 1/2</a>	<a href="#">Chembio HIV 1/2 Stat-Pak</a>	<a href="#">Clearview Complete HIV 1/2</a>	<a href="#">INSTI HIV-1 Antibody Test</a>	<a href="#">Alere Determine HIV-1/2 Ag/Ab Combo</a>	<a href="#">DPP HIV 1/2 Assay</a>
CLIA-WAIVED SPECIMEN COLLECTION METHODS	Venipuncture whole blood	✓	✓	✓	✓	✗	✗ <sup>2</sup>	✓
	Fingerstick whole blood	✓	✓	✓	✓	✓	✓	✓
	Oral fluid	✓	✗	✗	✗	✗	✗	✓
	Plasma	✗ <sup>2</sup>	✗ <sup>2</sup>	✗ <sup>2</sup>	✗ <sup>2</sup>	✗ <sup>2</sup>	✗ <sup>2</sup>	✗ <sup>2</sup>
	Serum	✗	✗ <sup>2</sup>	✗ <sup>2</sup>	✗ <sup>2</sup>	✗ <sup>2</sup>	✗ <sup>2</sup>	✗ <sup>2</sup>
WINDOW PERIOD <sup>3</sup>		Up to 3 months	Up to 3 months	Up to 3 months	Up to 3 months	Up to 3 months	Within 3 weeks in most cases	Up to 3 months
READ WINDOW <sup>4</sup>		20 – 40 min.	10 - 12 min.	15 - 20 min.	15 - 20 min.	2 – 5 min.	20 – 30 min.	Blood: 10–25 min. Oral: 25–40 min.
COST	Control kits	~ \$35 (~\$62.00 for shipping)	\$22.50 (Free shipping with test kits)	\$30	\$35 (Free shipping with test kits)	\$70 (\$50 for shipping)	\$35 (Free shipping)	\$30
	Test kits	\$12.50 (Free shipping)	\$8.25 (Free shipping)	\$5	\$9.25 (Free shipping)	\$8.99 - \$9.99 (\$50 shipping)	\$10 (Free shipping)	\$10
SHELF LIFE	Control kits	Unopened: 1 year Opened: 8 weeks	Unopened: 1 year Opened: 30 days	18-24 months opened or unopened	18-24 months opened or unopened	36 – 46°F: 28 days or ≤ -4°F: 1 year	24 months, opened or unopened	Until expiration date
	Test kits	30 months	12 months	24 months	24 months	12 months	12 months	Until expiration date

<sup>1</sup> CLIA stands for Clinical Laboratory Improvement Amendments. CLIA-waived rapid tests can be used in non-clinical settings (e.g., at community-based organizations, during outreach events). CLIA-waived tests are simple, low-risk tests that can be performed with minimal training and do not require centrifugation of specimens for testing. For more information about CLIA regulations, visit <http://bit.ly/CLIAregs>.

<sup>2</sup> Specimen collection method is not CLIA-waived, but may be performed in laboratories certified to conduct tests of moderate complexity.

<sup>3</sup> The time between first infection and when the test can reliably detect that infection.

<sup>4</sup> Period in which the test result must be interpreted after the test is run.

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TEMPERATURE LIMITATIONS	Control kit storage	36° - 46° F	36° - 46° F	36° - 46° F	36° - 46° F	36 - 46°F or ≤ -4°F	36 - 46°F	36 - 46°F
	Test kit storage	35° - 80° F	36° - 81° F	46° - 86° F	46° - 86° F	59° - 86°F	36 - 86°F	36 - 86°F
	Testing environment	59° - 99° F	59° - 81° F	64° - 86° F	64° - 86° F	59° - 86°F	59 - 86°F	64 - 86°F
SENSITIVITY <sup>5</sup> % (95% CI)	Venipuncture whole blood	Not evaluated	100% (99.5 - 100%)	99.7% (98.9 - 100%)	99.7% (98.9 - 100.0%)	99.4% (98.6 - 99.7%)	99.9% (99.4 - 100.0%)	99.9% (99.4 - 99.9%)
	Fingerstick whole blood	99.6% (98.5 - 99.9%)	Not evaluated	99.7% (98.9 - 100%)	99.7% (98.9 - 100.0%)	99.6% (98.9 - 99.9%)	99.9% (99.4 - 100.0%)	99.8% (99.2 - 99.9%)
	Oral fluid	99.3% (98.4 - 99.7%)	Not evaluated	Not applicable	Not applicable	Not applicable	Not applicable	98.9% (98.0 - 99.4%)
	Plasma	99.6% (98.9 - 99.8%)	100% (99.5 - 100%)	99.7% (98.9 - 100%)	99.7% (98.9 - 100.0%)	99.5% (98.8 - 99.8%)	99.9% (99.4 - 100.0%)	99.9% (99.4 - 99.9%)
	Serum	Not applicable	100% (99.5 - 100%)	99.7% (98.9 - 100%)	99.7% (98.9 - 100.0%)	99.0% (97.4 - 99.6%)	99.9% (99.4 - 100.0%)	99.9% (99.4 - 99.9%)
SPECIFICITY <sup>6</sup> % (95% CI)	Venipuncture whole blood	Not evaluated	99.8% (99.2 - 100%)	99.9% (99.6 - 100.0%)	99.9% (99.6 - 100.0%)	99.7% (99.4 - 99.8%)	99.7% (99.3 - 99.9%)	99.9% (99.7 - 99.9%)
	Fingerstick whole blood	100% (99.7 - 100%)	Not evaluated	99.9% (99.6 - 100.0%)	99.9% (99.6 - 100.0%)	99.3% (98.9 - 99.5%)	99.8% (99.5 - 99.9%)	100.0% (99.8 - 100%)
	Oral fluid	99.8% (99.6 - 99.9%)	Not evaluated	Not applicable	Not applicable	Not applicable	Not applicable	99.9% (99.7 - 99.9%)
	Plasma	99.9% (99.6 - 99.9%)	99.8% (99.2 - 100%)	Not evaluated	99.9% (99.6 - 100.0%)	99.96% (99.8 - 100%)	99.7% (99.2 - 99.8%)	99.9% (99.7 - 99.9%)
	Serum	Not applicable	99.7% (99.0 - 100%)	Not evaluated	99.9% (99.6 - 100.0%)	100% (99.6 - 100%)	99.6% (99.2 - 99.8%)	99.9% (99.7 - 99.9%)

<sup>5</sup> How often the test will correctly identify people who have established HIV-1 infection.

<sup>6</sup> How often the test will correctly identify people who are HIV negative.