

RAPID HIV TESTS SUITABLE FOR USE IN NON-CLINICAL SETTINGS (CLIA-WAIVED¹)

Updated November 2016

Brand		OraQuick Advance HIV 1/2 Antibody Test	Uni-Gold Recombigen HIV 1/2	Chembio HIV 1/2 Stat-Pak	Chembio Sure Check HIV 1/2	INSTI HIV-1/2 Antibody Test	Alere Determine HIV-1/2 Ag/Ab Combo	DPP HIV 1/2 Assay
CLIA-WAIVED SPECIMEN COLLECTION METHODS	Venipuncture whole blood	✓	✓	✓	✓	✗	✗ ₂	✓
	Fingerstick whole blood	✓	✓	✓	✓	✓	✓	✓
	Oral fluid	✓	✗	✗	✗	✗	✗	✓
	Plasma	✗ ₂	✗ ₂	✗ ₂	✗ ₂	✗ ₂	✗ ₂	✗ ₂
	Serum	✗	✗ ₂	✗ ₂	✗ ₂	✗ ₂	✗ ₂	✗ ₂
WINDOW PERIOD ³		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 ⁴		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 <i>(Public health pricing. Contact distributor for further details.)</i>	Control kits	~ \$35 (~\$62.00 for shipping)	\$22.50 (Free shipping with test kits)	\$46.85	\$46.85	\$22.99	\$35 (Free shipping)	\$46.85
	Test kits	\$12.50 (Free shipping)	\$8.25 (Free shipping)	\$5	\$5	\$7.99	\$10 (Free shipping)	\$5
SHELF LIFE	Control kits	Unopened: 1 year Opened: 8 weeks	Unopened: 1 year Opened: 30 days	1 year	1 year	1 year	24 months, opened or unopened	1 year
	Test kits	30 months	12 months	24 months	24 months	15 months	12 months	24 months

¹ 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>.

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

³ The time between first infection and when the test can reliably detect that infection.

⁴ 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	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 ⁵ % (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 ⁶ % (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%)

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

⁶ How often the test will correctly identify people who are HIV negative.