

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

Updated November 2024

Brand		OraQuick ADVANCE HIV 1/2 Antibody Test	OraQuick In-Home HIV Test	Chembio HIV 1/2 STAT-PAK	Chembio DPP HIV 1/2 Assay	Chembio SURE CHECK HIV 1/2 Assay	Chembio DPP HIV-Syphilis	INSTI HIV-1/2 Antibody Test	Abbott Determine HIV-1/2 Ag/Ab Combo
CLIA-WAIVED SPECIMEN COLLECTION METHODS	Venipuncture whole blood	✓	✓	✓	✓	✓	✗ ²	✗ ²	✗ ²
	Fingerstick whole blood	✓	✓	✓	✓	✓	✓	✓	✓
	Oral fluid	✓	✓	✗	✓	✗	✗	✗	✗
	Plasma	✗ ²	✗ ²	✗ ²	✗ ²	✗ ²	✗ ²	✗ ²	✗ ²
	Serum	✗	✗	✗ 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	Up to 3 months	Up to 3 months	Up to 3 months, early as 3 weeks
READ WINDOW ⁴		20 – 40 mins	20 – 40 mins	15 – 20 mins	Blood: 10–25 min. Oral: 25–40 min.	15 – 20 mins	10 – 25 mins	1 – 5 mins	20 – 30 mins
COST	Control kits	\$25 (Shipping depends)	N/A ⁵	\$72 (Shipping depends)	\$72 (Shipping depends)	\$72 (Shipping depends)	\$72 (Shipping depends)	\$76.99 Per box of 20 (Shipping depends)	\$68.95 (Shipping depends)
	Test kits	\$8 per test Either 25 or 100 order mins (Shipping depends)	\$28 per test (Shipping depends)	\$8.19 per test (Shipping depends)	\$8.19 per test (Shipping depends)	\$8.19 per test (Shipping depends)	\$14.31 per test (Shipping depends)	\$10.99 Per box of 50 (Shipping depends)	\$10.50 Per box of 25 (Shipping depends)
SHELF LIFE	Control kits	Unopened: 1 year Opened: 2 months	N/A ⁵	24 months	23 months	24 months	24 months	1 year	24 months
	Test kits	30 months	30 months	24 months	23 months	24 months	24 months	1 year	24 months
TEMPERATURE LIMITATIONS	Control kit storage	35° - 46° F	35° - 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	35° - 80° F	46° - 86°F	36° - 86°F	46° - 86°F	36° - 77° F	59° - 86°F	36° - 86°F
	Testing environment	59° - 99° F	59° - 99° F	64° - 86°F	64° - 86°F	64° - 86° F	64° - 86° F	59° - 86°F	59° - 86°F
SENSITIVITY ⁶ % (95% CI)	Venipuncture whole blood	Not evaluated	Not evaluated	99.7% (98.9 – 100%)	99.9% (99.4 – 99.9%)	99.7% (98.9 – 100%)	99.5% (98.6 – 99.8%)	99.9% (99.5 – 99.9%)	99.9% (99.4 – 100.0%)
	Fingerstick whole blood	99.6% (98.5 – 99.9%)	99.6% (98.5 – 99.9%)	99.7% (98.9 – 100%)	99.8% (99.2 – 99.9%)	99.7% (98.9 – 100%)	99.4% (98.4 – 99.8%)	99.8% (99.3 – 99.9%)	99.9% (99.4 – 100.0%)
	Oral fluid	99.3% (98.4 – 99.7%)	99.3% (98.4 – 99.7%)	Not applicable	98.9% (98.0 – 99.4%)	Not applicable	Not applicable	Not applicable	Not applicable
	Plasma	99.6% (98.9 – 99.8%)	99.6% (98.9 – 99.8%)	99.7% (98.9 – 100%)	99.9% (99.4 – 99.9%)	99.7% (98.9 – 100%)	99.3% (97.9 – 99.7%)	99.9% (99.5 – 100%)	99.9% (99.4 – 100.0%)
	Serum	Not applicable	Not applicable	99.7% (98.9 – 100%)	99.9% (99.4 – 99.9%)	99.7% (98.9 – 100%)	Not applicable	Not applicable	99.9% (99.4 – 100.0%)
SPECIFICITY ⁷ % (95% CI)	Venipuncture whole blood	Not evaluated	Not evaluated	99.9% (99.6 – 100%)	99.9% (99.7 – 99.9%)	99.9% (99.6 – 100%)	99.5% (98.9 – 99.8%)	100% (99.7 – 100%)	99.7% (99.3 – 99.9%)
	Fingerstick whole blood	100% (99.7 – 100%)	100% (99.7 – 100%)	99.9% (99.6 – 100%)	100% (99.8 – 100%)	99.9% (99.6 – 100%)	99.6% (99.1 – 99.8%)	99.5% (99.0 – 99.8%)	99.8% (99.5 – 99.9%)
	Oral fluid	99.8% (99.6 – 99.9%)	99.8% (99.6 – 99.9%)	Not applicable	99.9% (99.7 – 99.9%)	Not applicable	Not applicable	Not applicable	Not applicable
	Plasma	99.9% (99.6 – 99.9%)	99.9% (99.6 – 99.9%)	99.9% (99.6 – 100%)	99.9% (99.7 – 99.9%)	99.9% (99.6 – 100%)	99.6% (98.9 – 99.8%)	100% (99.7 – 100%)	99.7% (99.2 – 99.8%)
	Serum	Not applicable	Not applicable	99.9% (99.6 – 100%)	99.9% (99.7 – 99.9%)	99.9% (99.6 – 100%)	Not applicable	Not applicable	99.6% (99.2 – 99.8%)
Training		Virtual or In-person training provided	Virtual or In-person training provided	Virtual or In-person training provided	Virtual or In-person training provided	Virtual or In-person training provided	Virtual or In-person training provided	Virtual or In-person training provided	Virtual or In-person training provided

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.

⁵ FDA approved over-the-counter test and does not require a control.

⁶ How often the test will correctly identify people who have established HIV-1 infection.

⁷ How often the test will correctly identify people who are HIV negative.

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

Updated November 2024

Brand		Diagnostic Direct Syphilis Health Check	Chembio DPP HIV-Syphilis	NOWDiagnostics First To Know Syphilis Test
Cost	Control kits	\$55.00	\$72.00	N/A ⁵
	Test Kits	\$200.00 per box of 20 plus \$25 flat rate shipping	\$286.20 per box of 20 plus shipping \$499.00 per reader* *Test results must be read using a Chembio DPP Micro Reader. Each DPP Micro Reader can read 3000 test results.	\$17.50 per test shipping included
Shelf Life	Control Kits	Unopened: 24 months Opened: 1 year	24 months	N/A ⁵
	Test Kits	30 months	24 months	18 months
Contact		Jeff Tobias 866-358-9282 ext. 102 jtobias@dd-2u.com	Jonovan Acosta 951-475-8836 jacosta@chembio.com	T.J. Rivetti 971-582-7045 tj.rivetti@nowdx.com
Ordering		Contact Jeff Tobias or order on website	Contact Jonovan Acosta or order through a distributor	Contact T.J. Rivetti
Training		Virtual training provided	Virtual or In-person training provided	Virtual or In-person training provided