RAPID HIV TESTS SUITABLE FOR USE IN NON-CLINICAL SETTINGS (CLIA-WAIVED[1])

Updated April 2021

Brand		OraQuick Advance HIV 1/2 Antibody Test	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
CLIA-WAIVED SPECIMEN COLLECTION METHODS	**Venipuncture whole blood**	✓	✓	✓	✗	✗[2]
	Fingerstick whole blood	✓	✓	✓	✓	✓
	Oral fluid	✓	✗	✗	✗	✗
	Plasma	✗[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	Within 3 weeks in most cases
READ WINDOW[4]		20 – 40 min.	15 - 20 min.	15 - 20 min.	2 – 5 min.	20 – 30 min.
COST *(Public health pricing. Contact distributor for further details.)*	**Control kits**	$25	$50	$50	$34.95	$40-$50
	Test kits	$8 $28 At Home Kit	$5.50	$5.50	$12.62 - $15.95	$8
SHELF LIFE	**Control kits**	Unopened: 1 year Opened: 8 weeks	1 year	1 year	1 year	24 months, opened or unopened
	Test kits	30 months	24 months	24 months	15 months	12 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**	36º - 46º F	36º - 46º F	36º - 46º F	36 – 46°F	36 - 46°F
	Test kit storage	35º - 80º F	46º - 86º F	46º - 86º F	59° - 86°F	36 - 86°F
	Testing environment	59º - 99º F	64º - 86º F	64º - 86º F	59° - 86°F	59 - 86°F
SENSITIVITY[5] % (95% CI)	**Venipuncture whole blood**	Not evaluated	99.7% (98.9 – 100%)	99.7% (98.9 – 100.0%)	99.4% (98.6 – 99.7%)	99.9% (99.4 – 100.0%)
	Fingerstick whole blood	99.6% (98.5 – 99.9%)	99.7% (98.9 – 100%)	99.7% (98.9 – 100.0%)	99.6% (98.9 – 99.9%)	99.9% (99.4 – 100.0%)
	Oral fluid	99.3% (98.4 – 99.7%)	Not applicable	Not applicable	Not applicable	Not applicable
	Plasma	99.6% (98.9 – 99.8%)	99.7% (98.9 – 100%)	99.7% (98.9 – 100.0%)	99.5% (98.8 – 99.8%)	99.9% (99.4 – 100.0%)
	Serum	Not applicable	99.7% (98.9 – 100%)	99.7% (98.9 – 100.0%)	99.0% (97.4 – 99.6%)	99.9% (99.4 – 100.0%)
SPECIFICITY[6] % (95% CI)	**Venipuncture whole blood**	Not evaluated	99.9% (99.6 – 100.0%)	99.9% (99.6 – 100.0%)	99.7% (99.4 – 99.8%)	99.7% (99.3 – 99.9%)
	Fingerstick whole blood	100% (99.7 – 100%)	99.9% (99.6 – 100.0%)	99.9% (99.6 – 100.0%)	99.3% (98.9 – 99.5%)	99.8% (99.5 – 99.9%)
	Oral fluid	99.8% (99.6 – 99.9%)	Not applicable	Not applicable	Not applicable	Not applicable
	Plasma	99.9% (99.6 – 99.9%)	Not evaluated	99.9% (99.6 – 100.0%)	99.96% (99.8 – 100%)	99.7% (99.2 – 99.8%)
	Serum	Not applicable	Not evaluated	99.9% (99.6 – 100.0%)	100% (99.6 – 100%)	99.6% (99.2 – 99.8%)
Training		Virtual Training provided	Virtual or In-person Training provided	Virtual or In-person Training provided	Virtual Training provided	Virtual Training provided

[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.