

Comparison of Rapid Testing Technology
Offered by N.C. Rapid Testing Program

		OraSure Technologies OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test	Alere Determine™ HIV- 1/2 Ag/Ab Combo	Diagnostics Direct Syphilis Health Check™	OraSure Technologies OraQuick® HCV Rapid Antibody Test	INSTI HIV-1/HIV-2 Antibody Test
Specimen Collection	Venipuncture Whole Blood	Yes	Yes	No	No	Yes
	Fingerstick Whole Blood	Yes	Yes	Yes	Yes	Yes
	Plasma	Yes	Yes	Yes	Yes	Yes
	Serum	No	Yes	Yes	Yes	No
	Oral Fluid	Yes	No	No	No	No
Complexity	Waived	Oral fluid, Fingerstick whole blood, Venipuncture Whole Blood	Fingerstick whole blood	Fingerstick whole blood	Fingerstick whole blood, Venipuncture whole blood	Fingerstick whole blood
	Moderate	Plasma	Venipuncture whole blood, Plasma, Serum	Venipuncture whole blood, Plasma, Serum	N/A	Venipuncture whole blood, Plasma
Shelf Life	Control Kits	12 months unopened 8 weeks opened	18 months opened or unopened	24 months	12 months unopened 8 weeks opened	12 months
	Test Kits	24 months	24 months	24 Months	18 months	15 months
Temperature Requirements	Control Storage	2° to 8°C (35° to 46°F)	2° to 8°C (35° to 46°F)	2° to 8°C (35° to 46°F)	2° to 8°C (35° to 46°F)	2° to 30°C (35.6°-86°F)
	Test Kit Storage	2 to 27°C (35° to 80°F)	2 to 30°C (35° to 86°F)	4° to 30°C (39.2°-86°F)	2° to 30°C (35.6°-86°F)	2 to 30°C (35° to 86°F)
	Testing Environment	15° to 37°C (59° to 99°F)	15° to 30°C (59° to 86°F)	20° to 26°C (68° to 78.8°F)	15° to 37°C (59° to 99°F)	15° to 30°C (59°-86°F)
Time	Minimum Time for Development	20 minutes	20 minutes	10 minutes	20 minutes	1 minute
	Read Window	20 to 40 minutes	20 to 30 minutes	10 to 15 minutes	20 to 40 minutes	5 minutes
Sensitivity HIV-1 <small>(95% confidence limits)</small>	Venipuncture Whole Blood	99.6%	99.9%			99.9%
	Fingerstick Whole Blood	99.6%	99.9%	98%	98%	99.8%
	Plasma	99.6%	99.9%	99.9%	98%	99.9%
	Serum	N/A	99.9%	N/A	98%	N/A
	Oral Fluid	99.3%	N/A	N/A	N/A	N/A

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Specificity (95% confidence limits)	Venipuncture Whole Blood	100%	99.7%	100%	98%	100%
	Fingerstick Whole Blood	100%	99.8%	99.5%	98%	99.5%
	Plasma	99.9%	99.7%	100%	98%	100%
	Serum	N/A	99.6%	N/A	98%	N/A
	Oral Fluid	99.8%	N/A	N/A	N/A	N/A
Detection Time Frame* Days after HIV-1 RNA is detectable (~10 days)		23.7 days	Antigens 14-15 days; antigen & antibodies 21-28 days after infection (early infection).	N/A	N/A	21 days
HIV-2 Detection		Yes	Yes	N/A	N/A	Yes
Materials Provided in Test Kit (not including manufacturer supplied paperwork)		Test device, developer solution, reusable test stands, specimen collection loops	Test device, chase buffer, disposable capillary tubes, disposable workstations	Test device, disposable pipettes, diluent in dropper bottle containing saline buffer	Test device, buffer, pipette, moisture pad	Test device, membrane Unit, bottle 1, sample diluent (1.5ml), Bottle 2, color developer (1.5ml), bottle 3, clarifying solution (1.5ml), lancet, capillary test pipette, alcohol swab
Available Kit Sizes		100 test kits 25 test kits	100 test kits 25 test kits	20 test kits	25 test kits	50 test kits
Generation of detection		3rd generation lateral- flow	4 th generation lateral-flow	N/A	N/A	3 rd generation immunofiltration “flow- through”

*Median of 95% confidence intervals representing the estimated ranges of days that HIV-1 tests begin to detect HIV-1 infection AFTER HIV-1 RNA is detectable. The interval between HIV infection and the appearance of HIV-1 RNA is estimates to be around 10 days, but the absolute range is not yet known. See https://www.cdc.gov/hiv/pdf/testing/hiv-tests-advantages-disadvantages_1.pdf for further details.