

STANDARD Q

HIV 1/2 Ab 3-Line



STANDARD™ Q HIV 1/2 Ab 3-Line Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies specific to HIV-1 including subtype O and HIV 2 in human serum, plasma or venous and capillary whole blood. The test is for in vitro diagnostic use and intended as an aid to diagnosis of HIV in symptomatic, asymptomatic populations and persons at risk of HIV infection.

GENERAL INFORMATION:

- Getting a fast result in 10-20 minutes
- Easy handling which does not require specific training
- Suitable for Point Of Care Testing
- No follow-ups or equipments required
- Discrimination between HIV-1 and HIV-2 antibodies

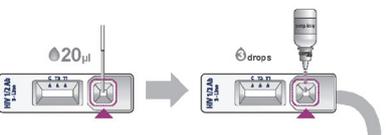
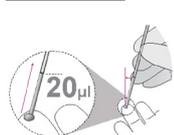


Specification

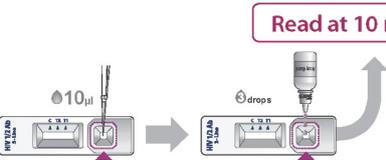
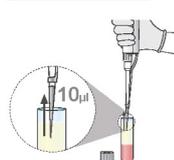
Specimen	Serum/Plasma/Whole Blood
Test Time	15 mins. (Do not read after 20 mins.)
Specimen Volume	Whole Blood: 20µl, Serum/Plasma: 10µl
Storage Temperature	2-40°C / 36-104°F

TEST PROCEDURE

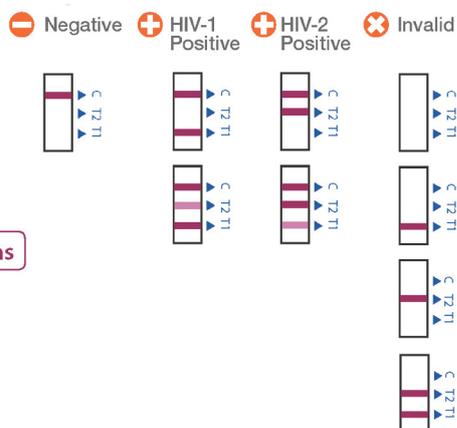
Whole blood



Serum / Plasma



Read at 10 mins



TEST PERFORMANCE (In accordance with CTS)

Sensitivity [95% CI]

Specificity [95% CI]

Total	99.8% [98.9-100%] (500/501)	Total	100% [99.6-100%] (1,898/1,900)
HIV-1 positive	99.7% (360*/361)	EDTA plasma	100% (1,000/1,000)
HIV-1 positive(non-B subtypes**)	100% (40/40)	Whole Blood	100% (500/500)
HIV-2 positive	100% (100/100)	Hospitalized patients	100% (200/200)
		Pregnant Woman	100% (200/200)

* The missed sample was collected from a patient receiving HAART very soon after seroconversion phase.

** non-B subtypes: A, A1, CRF01_AE, CRF02_AG, CRF06_cpx, CRF36_cpx, D, F1, F2, G, H, J, K, Group O

ORDERING INFORMATION

Category	Product	Pack Size
Blood Borne Disease	Device / Assay Diluent/Capillary Tube/Lancet/Alcohol Swab	25 Test
	Device / Assay Diluent	25 Test
	Multi Device / Assay Diluent	100 Test



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