

# STANDARD Q HCV Ab



STANDARD Q HCV Ab Test is a rapid chromatographic immunoassay for the qualitative detection of specific antibodies to HCV present in human serum, plasma or whole blood. This test is for in vitro professional diagnostic use and intended as an aid to early diagnosis of HCV infection in patients with clinical symptoms of HCV infection. It provides only an initial screening test result. STANDARD Q HCV Ab Test is intended to be used by trained healthcare or laboratory professionals or other health care workers who have received appropriate training. This product is not intended for self-testing.

### GENERAL INFORMATION:

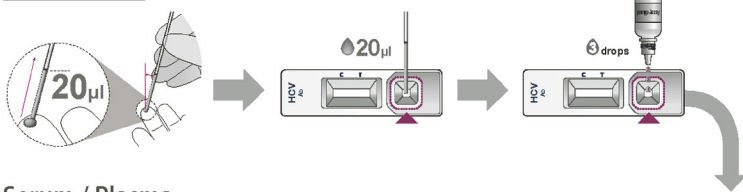
- Easy to use, Easy to read and interpret
- Room temperature storage



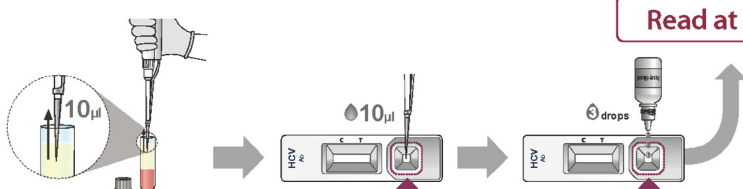
Specification	
Specimen	Plasma/Whole Blood
Test Time	5 mins. (Do not read after 20 mins.)
Specimen Volume	10µl
Storage Temperature	2-40°C / 36-104°F

### TEST PROCEDURE

#### Whole blood



#### Serum / Plasma



### INTERPRETATION



### TEST PERFORMANCE (In accordance with CTS)

Detection of HCV Ab			
	Sensitivity [95% CI]		Specificity [95% CI]
Total	100% [99.1-100%] (413/413)	Total	97.67% [99.6-100%] (1,465/1500)
HCV positive	100% (311/311)	EDTA plasma	97.2% (972/1,000)
HCV (genotypes*)	100% (102/102)	Whole Blood	99.6% (493/500)

\* HCV genotypes: 1, 1a, 1b, 2a, 2c, 2b, 3, 3a, 3k, 4a, 4c, 4d, 4e, 4h, 5, 5a, 6, 6a

### ORDERING INFORMATION

Category	Contents	Pack Size
Hepatitis	Device/Assay Diluent/Capillary Tube	25 Test
	Device/Assay Diluent	25 Test
	Multi Device/Assay Diluent	100 Test