

H.pylori Antibody Rapid Test Cassette (WB/S/P)

The H.pylori Antibody Rapid Test Cassette is a lateral flow chromatographic immunoassay for the qualitative detection of antibodies to H.pylori in human Whole Blood/Serum/Plasma. It provides an aid in the diagnosis of infection with H.pylori.



● Component



Test Cassette



Dropper



Buffer



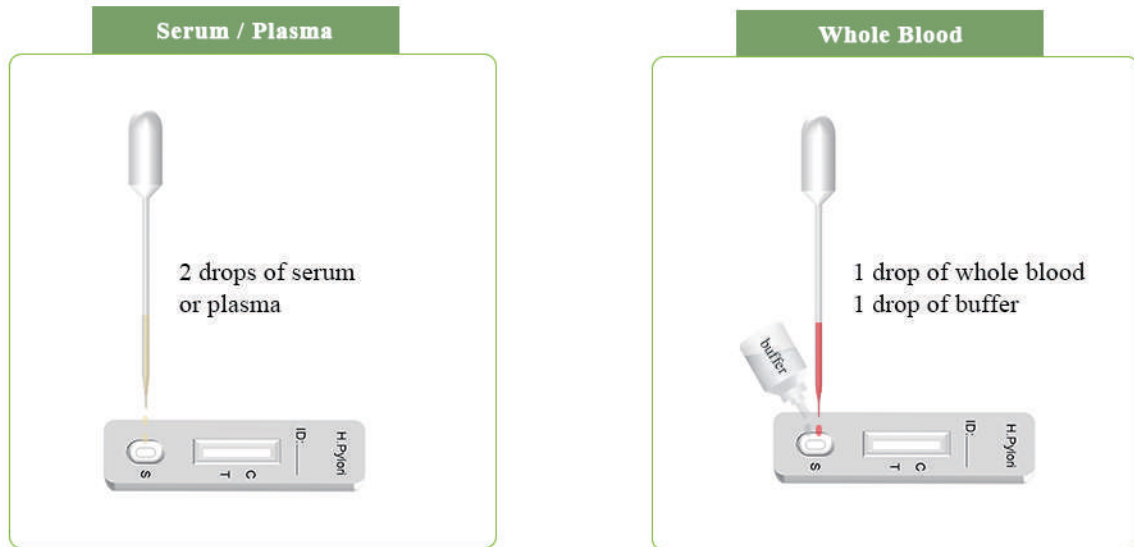
40/25 Tests/box

Accurate

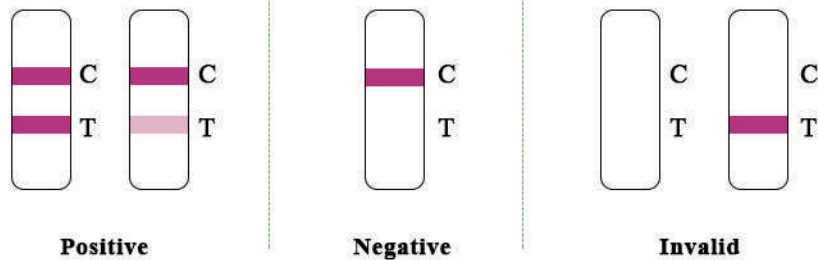
Quick

Simple

● Test Procedure



Interpretation of Results



● Performance

Accuracy

1030 clinical Specimens from three Professional Point of Care sites were evaluated with the H.pylori Antibody Rapid Test and commercial kit. The results are as below:

Agreement with Commercial H.pylori Rapid Test

		Commercial H.pylori Rapid Test		Total
		Positive	Negative	
CLUNGENE®	Positive	319	10	329
	Negative	2	699	701
Total		321	709	1030

The agreement between these two devices is 99.38% for positive specimens, and 98.59% for negative specimens.

Agreement with ELISA

		ELISA		Total
		Positive	Negative	
CLUNGENE®	Positive	323	6	329
	Negative	2	699	701
Total		325	705	1030

A statistical comparison was made between the results yielding a clinical sensitivity of 99.38%, a clinical specificity of 99.15% and an accuracy of 99.22%.