



EZER™

H. pylori

Antigen Rapid Test



INTENDED USE

The EZER™ *H. pylori* Antigen Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of *Helicobacter pylori* (*H. pylori*) antigens in human feces specimens to aid in the diagnosis of *H. pylori* infection.



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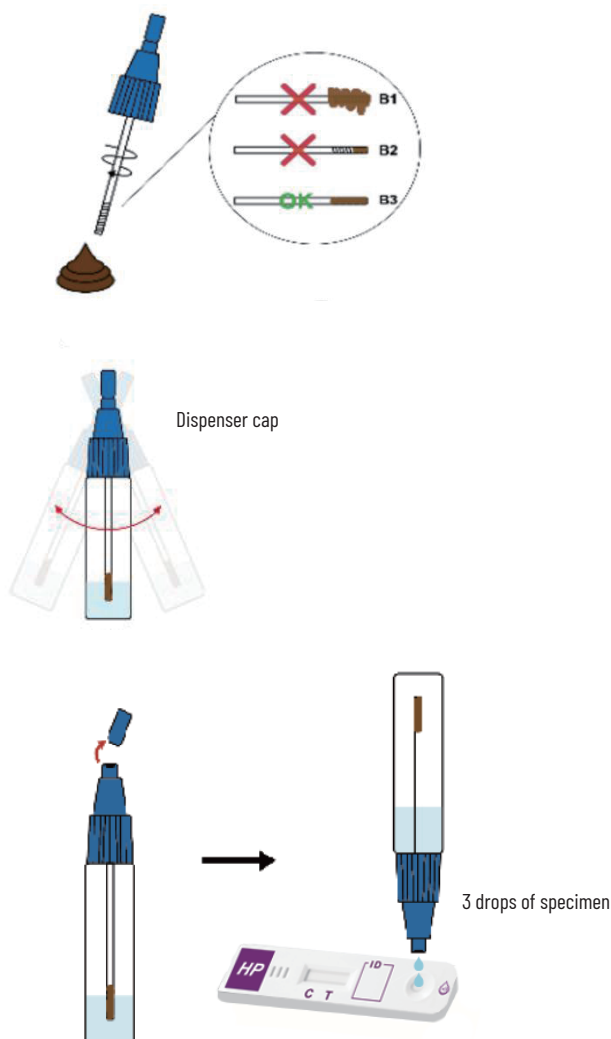
PERFORMANCE CHARACTERISTICS

Results		Wondfo H. Pylori Antigen		
		+	-	Total
EZER™ H. Pylori Antigen	+	419	13	432
	-	9	820	829
	Total	428	833	1261

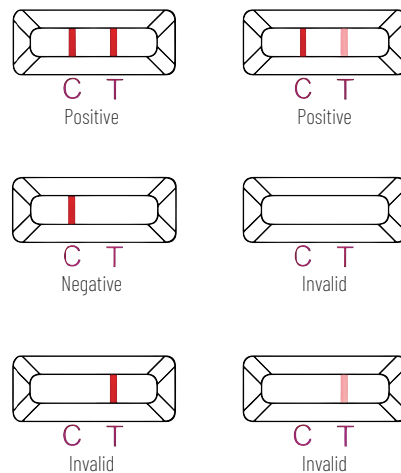
Relative Sensitivity : 97.90% (95%CI*: 96.05% ~ 99.03%)
 Relative Specificity : 98.44% (95%CI*: 97.35% ~ 99.17%)
 Accuracy : 98.26% (95%CI*: 97.37% ~ 98.90%)

PROCEDURE

Reagents, specimens, and devices must be at room temperature (15–30 °C) for testing.



RESULTS



AVAILABILITY

Product	EZER™ H. pylori Antibody Rapid Test
Cat. No.	P221007
Test Device	20
Stool Collection Tube	20
Package Insert	1