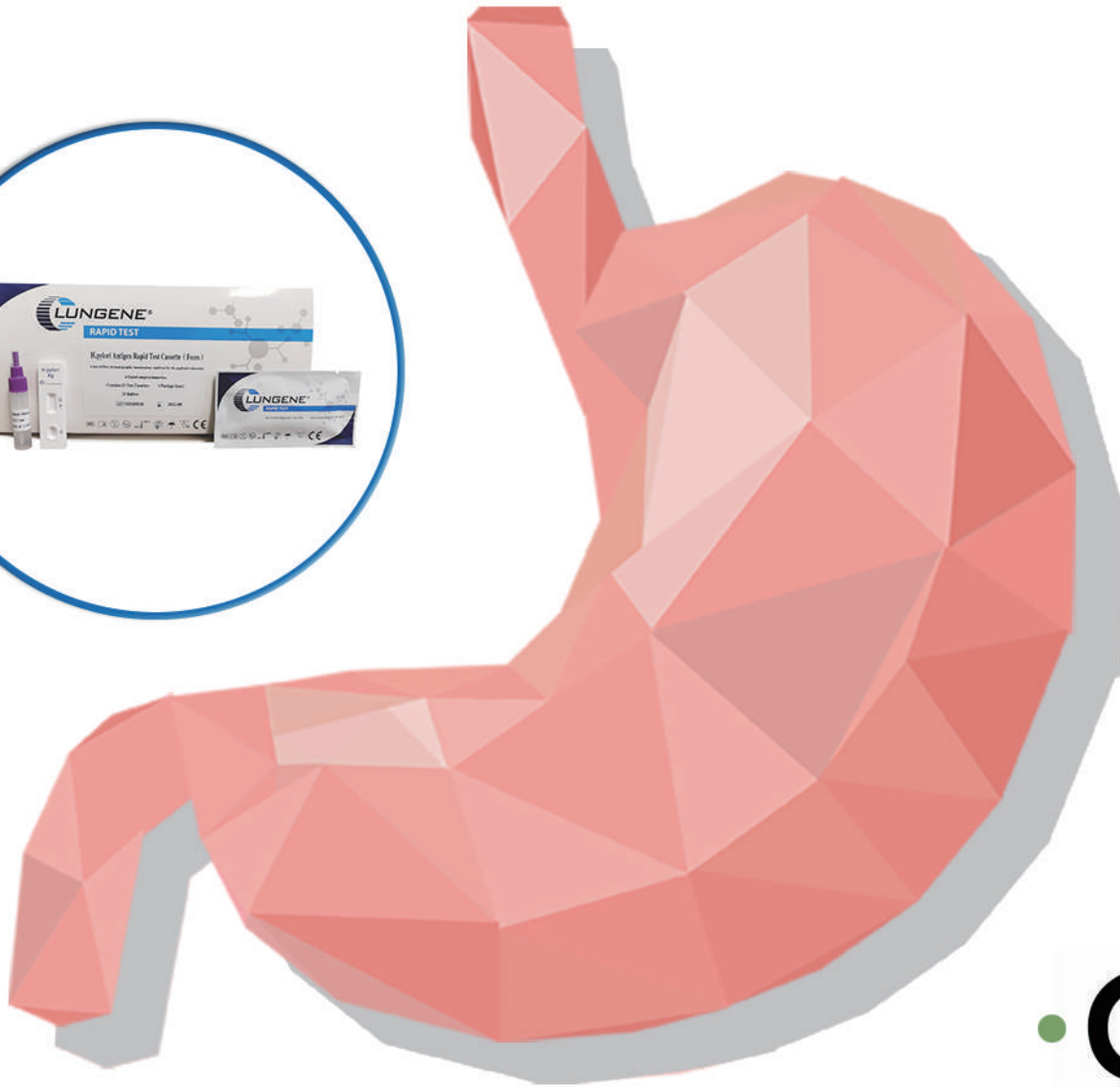




Accurate
Rapid
Simple

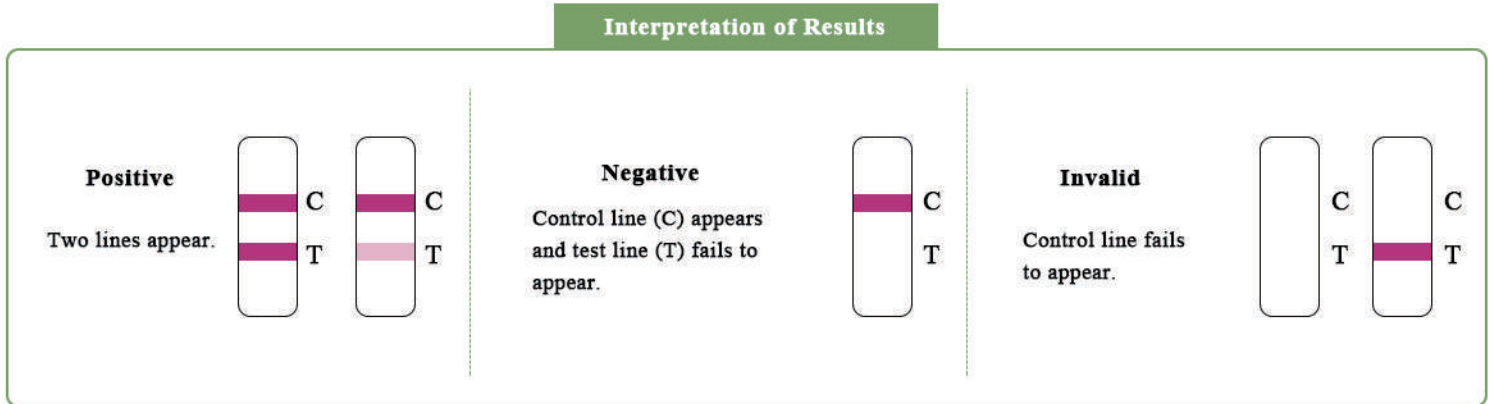


H.pylori Antigen Rapid Test Cassette (Feces)

The H.pylori Antigen Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of H.pylori antigen in human feces specimens to aid in the diagnosis of H.pylori infection.

Test Procedure

- Collect sufficient quantity of feces (1-2ml or 1-2g) in a clean, dry specimen collection container to obtain maximum antigens (if present). Best results will be obtained if the assays performed within 6 hours after collection.



Performance

Accuracy

- 1068 clinical Specimens from three Professional Point of Care sites were evaluated with the H.pylori Antigen Rapid Test and commercially available H.pylori Ag tests. The following results are tabulated from these clinical studies:

Agreement with Commercial H.pylori Ag Test

		Commercial H.pylori Ag Test		Total
		Positive	Negative	
CLUNGENE®	Positive	467	1	468
	Negative	2	598	600
Total		469	599	1068

The agreement between these two test kit is 99.57% for positive specimens, and 99.83% for negative specimens.

This study demonstrated that the H.pylori Antigen Rapid Test is substantially equivalent to the commercial device.

Cross Reactivity and Interference

18 kinds of organisms, 6 kinds of potentially cross-reactive endogenous substances and 13 kinds of common biological analytes were tested with the H.pylori Antigen Rapid Test. No cross reactivity or interference was observed.