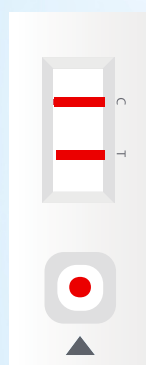


H. Pylori AB Rapid Test Kit (Serum/Plasma/Whole Blood)

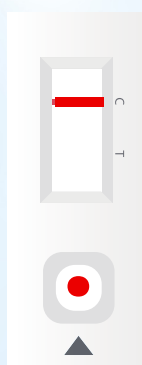
INTERPRETATION OF RESULTS

Figure 1



POSITIVE

Figure 2



NEGATIVE

Figure 3



INVALID

← BLOOD SAMPLE

← BLOOD SAMPLE

← BLOOD SAMPLE

DIRECTIONS FOR USE

Allow the test device, specimen and/or buffer to equilibrate at room temperature (15-30°C) before testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within 1 hour.
2. Place the cassette on a clean and level surface.
3. For Serum or Plasma specimen: Place the cassette on a clean and level surface. For Serum or Plasma specimen: Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 10 µL) to the specimen well, then add 2 drop of buffer (approximately 80 µL) and start the timer.
4. Wait for the colored line(s) to appear. Read results at 15 minutes. Note: Do not interpret the result after 20 minutes.



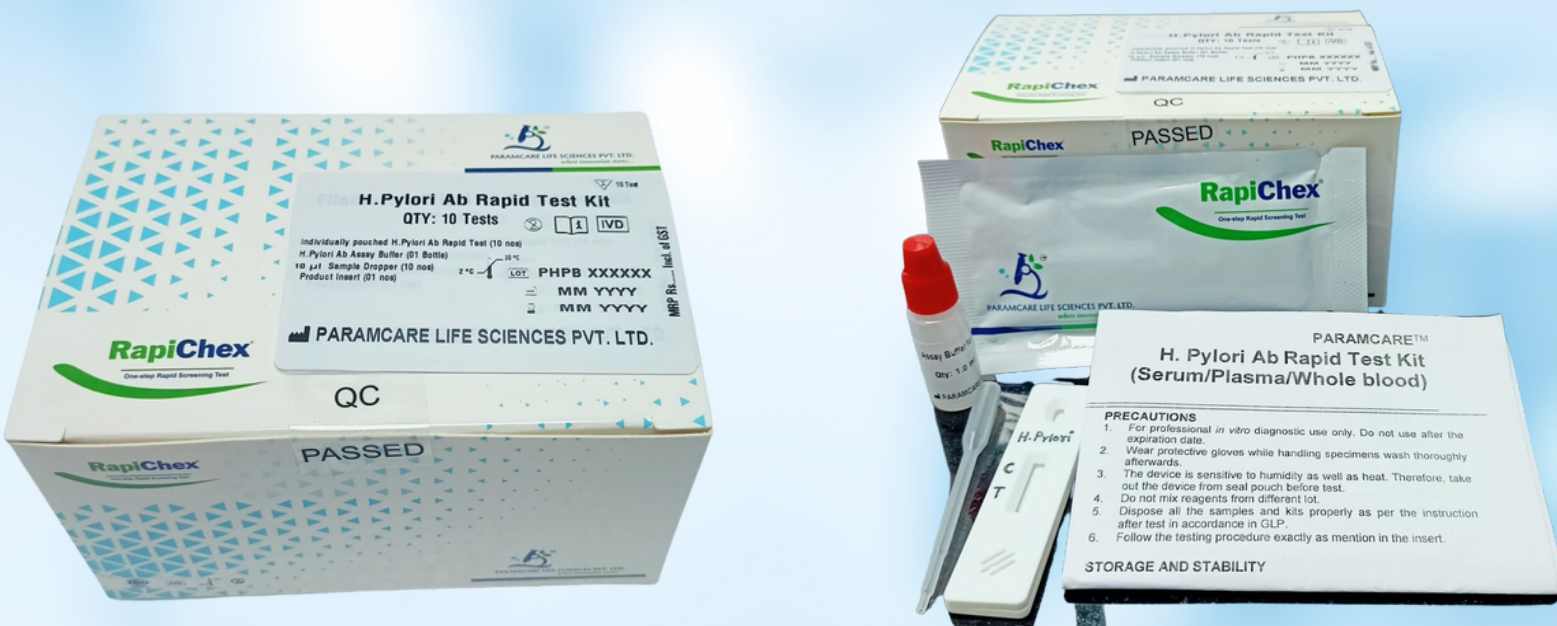
Positive: The control line (C) and test line (T) lines are visible on the test device. This is positive for cTnT antigen.

Negative: The control line is the only visible line on the test device. No cTnT antigen were detected.

Invalid: The control line fails to appear.

H. Pylori AB Rapid Test Kit (Serum/Plasma/Whole Blood)

H. Pylori AB Rapid Test Kit



Sensitivity and Specificity

Method		Other Rapid Test		Total Test
H.Pylori Ab Rapid Card Test	Result	Positive	Negative	
	Positive	73	2	75
	Negative	2	198	200
Total Results		75	200	275

Relative Sensitivity: 97.3% (95% CI: 97.8-98.9%)

Relative Specificity: 99% (95% CI: 98.8-99.9%)

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Gujarat, 396191.