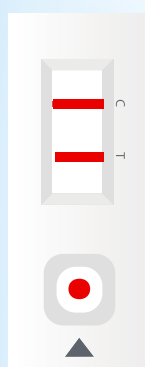




Immunoglobulin E (IgE) Rapid Test Kit (Serum/Plasma/Whole Blood)

INTERPRETATION OF RESULTS

Figure 1



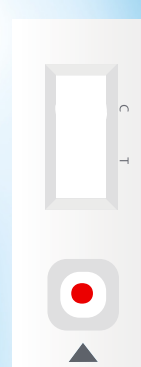
POSITIVE

Figure 2



NEGATIVE

Figure 3

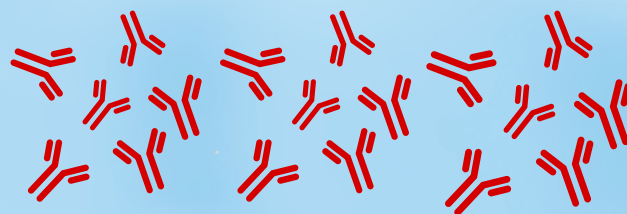


INVALID

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: Hold the dropper vertically and transfer 1 drops of serum or plasma (approximately 25µL) into the specimen well, and start the timer.
For Venipuncture/Finger prick Whole Blood specimen : Hold the dropper vertically and transfer 1 drops of whole blood (approximately 25µL) to the specimen well, then add 1 drop of buffer (approximately 40µL), and start the timer.
4. Wait for the colored line(s) to appear. Read results at 5 minutes. Note: Do not interpret the result after 10 minutes.



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

Negative: The control line is the only visible line on the test device. No human IgE Ab antibodies were detected.

Invalid: The control line fails to appear.

Immunoglobulin E (IgE) Rapid Test Kit (Serum/Plasma/Whole Blood)

Immunoglobulin E (IgE) Rapid Test Kit



Sensitivity and Specificity

Method		Other Rapid Test		Total Test
IgE Rapid Card Test	Result	Positive	Negative	
	Positive	75	0	75
	Negative	0	230	230
Total Results		75	230	305

SENSITIVITY : >98% (95% CI*: 94.4%-99.8%)

SPECIFICITY : >98% (95% CI*: 96.7%-99.6%)

Corporate Office:-

C/609, 6th Floor, Mittal Commercial, Unit 2, Hasan Pada Road, Chimatpada Marol, Andheri (E), Mumbai - 400059.

Factory Address:-

G/F- 12/13, Evershine-2, Survey NO. 307/3/1, Balitha, N.H No 48, Vapi, Valsad, Gujarat, 396191.