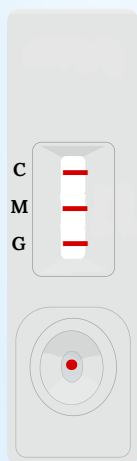


## Leptospira IgG/IgM Ab Rapid TestKit (Serum/Plasma/Whole Blood)

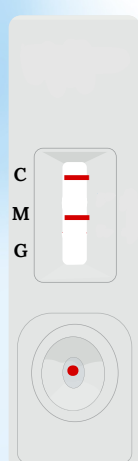
### INTERPRETATION OF RESULTS

Figure 1



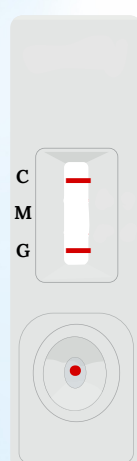
**IgM/IgG POSITIVE**

Figure 2



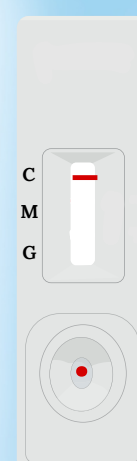
**IgM POSITIVE**

Figure 3



**IgG POSITIVE**

Figure 4



**NEGATIVE**

### 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 5 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.

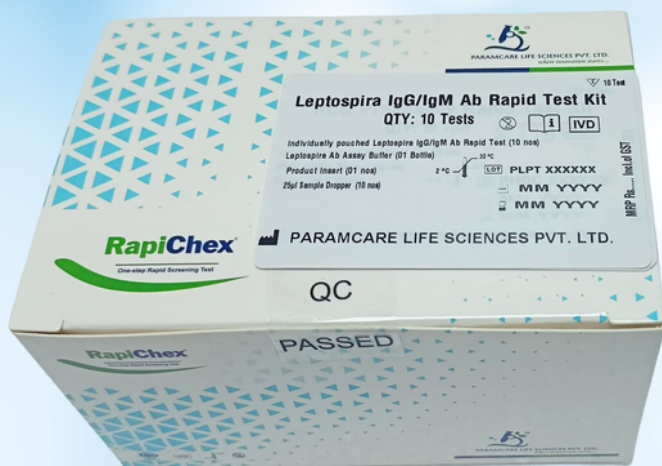
- 1) **IgM POSITIVE:** Two distinct red lines appear. The control line (c) and IgM (G) line are visible.
- 2) **IgG POSITIVE:** IgM Positive the control line (C) and IgM line (M) are visible. This is positive for IgG antibodies.
- 3) **IgG/IgM POSITIVE:** IgG and IgM Positive The control line (C), IgM (M) and IgG line (G) are visible. This is positive for both IgM and IgG antibodies.
- 4) **NEGATIVE:** One distinct red line appears. The control line (c) is the only line visible. No IgM/IgG antibodies were detected.
- 5) **INVALID:** Control line fails to appear. The test results are INVALID, if no control line (C) is visible.

## Leptospira IgG/IgM Ab Rapid TestKit (Serum/Plasma/Whole Blood)



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### Leptospira IgG/IgM Ab Rapid TestKit



## Sensitivity and Specificity

	Clinical performance for IgM Test		
IgM EIA	Positive	Negative	Total
Positive	50	0	50
Negative	0	230	230
Total	50	230	280

	Clinical performance for IgG Test		
IgG EIA	Positive	Negative	Total
Positive	70	0	70
Negative	0	230	230
Total	70	230	300

**IgM Relative Sensitivity: 100% (95% CI: 98.8-99.9%)**

**IgG Relative Sensitivity: 100% (95% CI: 98.8-99.9%)**

**Relative Specificity: 100% (95% CI: 98.8-99.9%)**

### Corporate Office:-

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### Factory Address:-

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Valsad, Gujarat, 396191.