

INTERPRETATION OF RESULTS



Figure 1

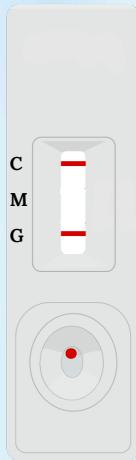


Figure 2

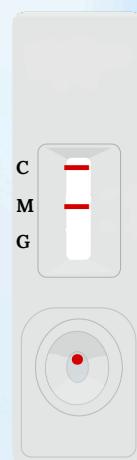


Figure 3

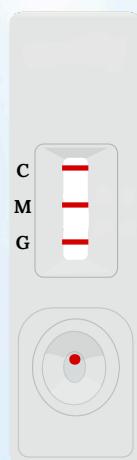


Figure 4

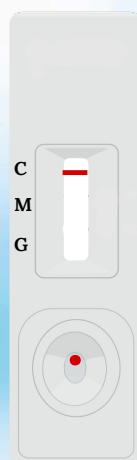
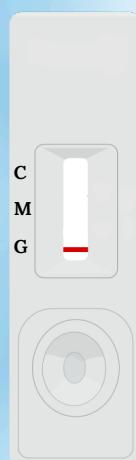


Figure 5



IgG POSITIVE

IgM POSITIVE

IgG/IgM POSITIVE

NEGATIVE

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: 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) **IgG POSITIVE:** Two distinct red lines appear. The control line (c) and IgG (G) line are visible.
- 2) **IgM POSITIVE:** IgM Positive the control line (C) and IgM line (M) are visible. This is positive for IgM 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.

Leishmania IgG/IgM Ab Rapid Test Kit



Sensitivity and Specificity

		Clinical performance for IgM Test		
IgM Rapid Test	Positive	Negative	Total	
Positive	26	0	26	
Negative	2	223	225	
Total	28	223	251	

		Clinical performance for IgG Test		
IgG EIA	Positive	Negative	Total	
Positive	22	0	22	
Negative	2	223	225	
Total	23	224	247	

IgM Relative Sensitivity: 100%
IgG Relative Sensitivity: 100%

Relative Specificity: 99.11%

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