QUANTON BIOLIFE SCIENCES

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Leptospira IgG/IgM Ab Rapid Test Kit (Serum/Plasma/Whole blood)

QBL/LEP/RPT_40

The Leptospira IgG/IgM Ab Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to Leptospira *interrogans* in human serum/plasma/whole blood specimens.

For *In-Vitro Diagnostic* Use only

ORDER INFORMATION

Pack Size	REF
01 Test	PLPT 01
05 Tests	PLPT 05
10 Tests	PLPT 10
25 Tests	PLPT 25
50 Tests	PLPT 50

CLINICAL SIGNIFICANCE

Leptospirosis occurs worldwide and is a common mild to severe health problem for humans and animals, particularly in areas with hot and humid climates. The natural reservoirs for leptospirosis are rodents as well as a large variety of domesticated mammals. Human infection is caused by *Leptospira interrogans*, the pathogenic member of the genus of Leptospira. The infection is spread via urine from the host animal. After infection, leptospires are present in the blood until they are cleared approximately 4 to 7 days after the onset of the disease following the production of anti-L. interrogans antibodies. Antibodies to Leptospira are detectable by the 6th to 10th day of disease and levels peak within 3 to 4 weeks and then gradually decline. Antibodies may be detectable for years post infection. IgM anti-Leptospira are detectable during the first week of illness allowing early therapeutic intervention at a time point where it is most effective. IgG class antibodies appear at a later time point of infection and may be persist for several years.

PRINCIPLE

Leptospira IgG/IgM Ab Rapid Test has 3 pre-coated lines, "G" (*Leptospira interrogans* IgG Test Line), "M" (*Leptospira interrogans* IgM Test Line) and "C" (Control Line) on the surface of the strip. Along with it the test device consists of a colored conjugate pad containing L. interrogans antigens conjugated with colloidal gold (Leptospira conjugates) and a control antibody conjugated with colloidal gold. When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. Anti-L. interrogans IgM, if present in the specimen, will bind to the Leptospira conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM antibody forming a colored M line, indicating an anti-L. interrogans IgM positive test result. Anti-L. interrogans IgG, if present in the specimen, will bind to the Leptospira conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgG forming a colored G line, indicating an anti-L. interrogans IgG positive test result.
Absence of any test lines (M and G) suggests a negative result. The test contains an internal control (C line) which should exhibit a colored line of the immunocomplex of the control antibodies regardless of color development on any of the test lines. If the C line does not develop, the test result is invalid and the specimen must be retested with another device.

KIT COMPONENTS

• Test Cassettes • Droppers • Buffer • Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

• Specimen Collection Containers • Centrifuge (For plasma only) • Timer

PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Wear protective gloves while handling specimens wash thoroughly afterwards.
3. The device is sensitive to humidity as well as heat. Therefore, take out the device from seal pouch before test.
4. Do not mix reagents from different lot.
5. Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
6. Follow the testing procedure exactly as mention in the insert.

STORAGE AND STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test kit, if the pouch is damaged or seal is broken.

SPECIMEN COLLECTION & PREPARATION

The Leptospira IgG/IgM Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum and plasma specimen.

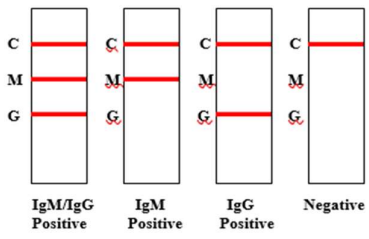
- **Serum (S):** Collect the whole blood into a collection tube (NOT containing anticoagulants such as heparin, EDTA, and sodium citrate) by vein puncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
- **Plasma (P):** Collect the whole blood into a collection tube (containing anticoagulants such as EDTA K2, Heparin sodium, Citrate sodium and Oxalate potassium) by vein puncture and then centrifuge blood to get plasma specimen.
- **Whole Blood (WB):** Both Fingerstick Whole Blood and Venipuncture Whole Blood can be used.

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 (upto mark) of serum or plasma (approximately 5 µL) to the specimen well, then add 2 drops of buffer (approximately 80 µL) and start the timer
4. **For Venipuncture Whole Blood specimen**: Hold the dropper vertically and transfer 1 drop of whole blood (approximately 5µL) to the specimen well, then add 2 drops of buffer (approximately 80 µL) and start the timer
   For Fingerstick Whole Blood specimen: Take sample using sample dropper and transfer approximately 5 µL (1 drop) of fingerstick whole blood specimen to the specimen well of test cassette, then add 2 drop of buffer (approximately 80 µL) and start the timer.
5. Wait for the colored line(s) to appear. Read results at 15 minutes.
   Note: Do not interpret the result after 15 minutes.

INTERPRETATION OF RESULTS



1) **IgM POSITIVE:** Two distinct red lines appear. The control line (c) and IgM (M) line are visible on the test cassette. This is positive for IgM antibodies to *Leptospira interrogans.*

2) **IgG POSITIVE:** IgG Positive the control line (C) and IgG line (G) are visible on the test device. This is positive for IgG antibodies to *Leptospira interrogans.*

3) **IgG/IgM POSITIVE:** IgG and IgM Positive The control line (C), IgM (M) and IgG line (G) are visible on the test device. This is positive for both IgM and IgG antibodies to *Leptospira interrogans*

4) **NEGATIVE:** One distinct red line appears. The control line (c) is the only line visible on the test cassette. No IgM/IgG antibodies were detected. The result does not exclude Leptospira infection.

5) **INVALID:** Control line fails to appear. The test results are INVALID, if no control line (C) is visible, regardless of the presence or absence of line in the IgM(M)/IgG(G) region of the cassette. Repeat the test using a new cassette.

Quality Control

Internal procedural controls are included in the test individually. A colored line appearing in control line region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Limitations of the Test

1. The test procedure, precautions and interpretation of results for this test must be followed when testing.
2. The Leptospira IgG/IgM Ab Rapid Test (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for detection of antibodies for Leptospira in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of Leptospira can be determined by this qualitative test.
3. A negative result can occur if the quantity of the anti- Leptospira antibodies present in the specimen is below the detection limits of the assay or the antibodies that are detected are not present during the stage of disease. Other clinically available tests are required. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

A total of 250 specimens were collected from susceptible subjects and tested by Leptospira IgG/IgM Ab Rapid Test and a commercial Leptospira IgG and IgM Ab EIA Test as reference. Comparison for all subjects is showed in the following table.

	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%), Overall Agreement: 100% (95% CI: 98.8-99.9%)

Cross-reactivity

The Leptospira IgG/IgM Ab Rapid Test Cassette (Serum/Plasma/Whole Blood) has been tested HBsAg, anti-HIV, anti-HCV, anti-RF, anti-Spyhilis, anti-H.pylori, anti-Toxo IgG positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have also been tested using the Leptospira IgG/IgM Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) and no interference was observed. Caffeine: 20mg/dl, Creatine: 200mg/dl, Acetylsalicylic Acid: 20mg/dl, Gentisic Acid: 20mg/dl, Albumin: 2000mg/dl, Ascorbic Acid: 2g/dl, Hemoglobin: 1000mg/dl, Oxalic acid: 600mg/dl, Bilirubin: 1000mg/dL, Triglycerides: 1600mg/dl & Cholesterol: 800mg/dl

BIBLIOGRAPHY

1. Stallman GND. The International Committee on Systematic Bacteriology: Subcommittee on the Taxonomy of Leptospira. Int J Syst Bacteriol 1987; 37:472.
2. Ahmad SN, Shah S, Ahmad FMH. Laboratory diagnosis of Leptospirosis. J Postgrad Med 2005; 51:195-200.
3. Adler B, Murphy AM, Locarnini SA, Faine S. Detection of specific anti-leptospiral immunoglobulins M and G in human serum by solid-phase enzyme-linked immunosorbent assay. J Clin Microbiol. 1980; 11:452–457.

GLOSSARY OF SYMBOL

	Consult Instruction for Use
REF	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight

Paramcare Life Sciences Private Limited, G/F-12/13, Evershine-2, Survey No. 307/3/1, Balitha N.H No 48, Vapi, Valsad, Gujarat, 396191.

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