

LEPTOSPIRA CARD (IgG/IgM)

[Whole Blood/Serum/Plasma]

IMMUNOPAK

Last update 04-2023

Ref. RDT-LPT.110, 10 Test

INTENDED USE

Leptospira (IgG/IgM) rapid test kit for IgG and IgM antibody against Leptospira interrogans in whole Blood/Serum/Plasma

INTRODUCTION

Leptospira IgG/IgM is a chromatographic immunoassay kit for rapid and differential detection kit of immunoglobulin G (IgG) and immunoglobulin M (IgM) against Leptospira interrogans in human serum or plasma. This test is intended for professional use as an aid in the clinical laboratory diagnosis of patients with clinical symptoms consistent with leptospirosis. This test provides only a preliminary test result. Therefore, other serological test like MAT reference test, ELISA, PHA must be used in order to obtain a confirmation of Leptospira interrogans infection.

L.interrogans-specific antigen complexes with gold conjugate is placed in the conjugate pad and anti-human IgG and anti-human IgM are coated on the membrane. When antibody-positive specimen is loaded into sample well, the antibodies will bind to L.interrogans-specific antigen-gold complex.

The immune complex is then capture at test line region (G&M) to make a visible pink-purple line in the test line regions.

To serve as a procedural control, an additional line of Goat anti-mouse IgG has been immobilized on the card. If the test is performed correctly, this will result in the formation of pink-purple line upon contact with the conjugate as a control line.

PRESENTATION

	10 Test
Leptospira Card	10 Cards
Assay buffer	1 Vial

PRECAUTION

1. The presence of humidity may decrease the stability of the reagents. Thus, please carry out the test immediately after removing the device from the foil pouch.
2. Do not use the kit after the expiration date and do not freeze the kit.
3. For *in-vitro* diagnostic use only. Do not re-use the test device.
4. Wear protective gloves while handling samples and wash hands thoroughly after the test.
5. Dispose gloves, swabs, test tubes, and the used strips properly after test, in accordance with GLP.
6. Do not eat or smoke while handling specimens.
7. Decontaminate and dispose of all specimens and reaction waste should be done in a biohazard container.

STORAGE AND STABILITY

Leptospira IgG/IgM test card should be stored at 2°C-40 °C. The card may be stored at room temperature but not exceeding 40 °C in the original sealed pouch. The shelf life or expiry of the card is printed on Pouch as well as carton label. The test kit should be kept away from direct sunlight, moisture and heat.

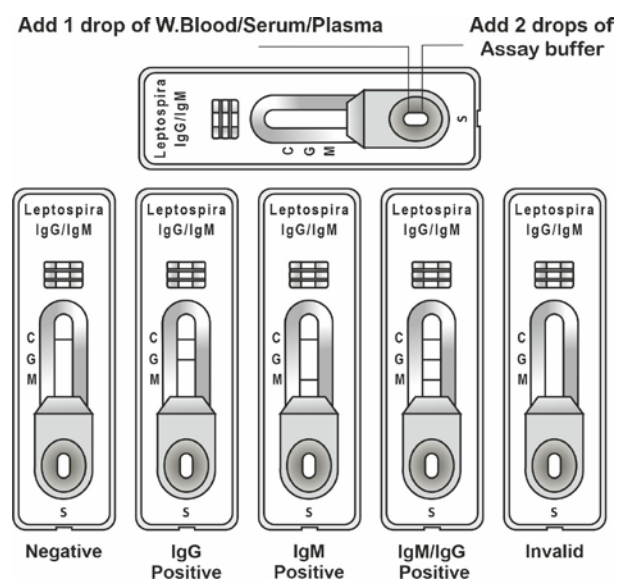
SPECIMEN COLLECTION AND STORAGE

1. Specimen to be tested should be obtained and handled by standard methods for their collections.
 - **Whole blood as specimen**
 1. Fresh blood from finger prick/puncture may be used as a test specimen.
 2. Collection of whole blood as a test specimen; EDTA, heparin or oxalate can be used as a suitable anticoagulant.
 - **Serum:** allow the blood to clot, then centrifuge to separate the serum.
 - **Plasma:** collect the whole blood into the tube containing anticoagulants such as heparin, citrate, or EDTA. Centrifuge the blood and separate the plasma.
2. All specimens should be tested as soon as they are prepared. If necessary, they may be stored at 2-8 °C for up to 24 hours or at -20°C for longer periods.

PROCEDURE

1. Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.
2. When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.
3. Fill the pipette dropper with the specimen. Holding the dropper vertically, add 1 drop (about 25-30 µl) of specimen (W.B./Serum/Plasma) into the sample well making sure that there are no air bubbles. Then add 2 drops (Approx. 75-80 µl) of Assay buffer immediately.
4. Read the results within 15 minutes. Positive results can be visible in as short as 1 minute. Don't read result after 15 minutes. To avoid confusion, discard the test device after interpreting the result.

INTERPRETATION OF THE RESULTS



LEPTOSPIRA CARD (IgG/IgM)

[Whole Blood/Serum/Plasma]

IMMUNOPAK

Last update 04-2023

- **Negative:** Only one pink-purple line in the control line (C). No *L.interrogans* specific IgG and IgM were detected.
- **IgM Positive:** Two pink-purple lines are appeared in the IgM line (M) and control line (C). This is positive for IgM antibodies to *L.interrogans* and indicative of an acute *L.interrogans* infection.
- **IgG Positive:** Two pink-purple lines are appeared in the IgG line (G) and control line (C). This is positive for IgG antibodies and indicative of a secondary or previous *L.interrogans* infection.
- **IgG and IgM Positive:** Three pink-purple lines are appeared in the IgG line (G), IgM line (M) and control line (C). This is positive for both IgG and IgM antibodies to *L.interrogans*.
- **Invalid:** If no line or only T line is visible within the window after performing the test, the result is considered invalid. If the test is invalid, a new test should be performed with a new patient sample and a new test cassette.

REFERENCES

1. Auran, N.E., R.C.Johnson,D.M.Ritzi (1972) Infect. Immunity.5:968-9997555.
2. Joseph L.S., Richard C.H., C.D. Cox (1973) Infect. Immunity.7(7):886-897.
3. Adler B.,Faine S., Gordon L.M.(1981) Aust.Vet.J.,57:414-417.
4. Bolin C.A., Zuerner R.L., Trueba G. (1989) Am.J.Vet.Res. 50: 1001-1003.
5. Cho, H.J., Gale, S.P., Masri, S.A., Malkin, K.L., (1989) Can.J.Vet. Res. 53:285-289.



Regd. Office.3/7, B.I.D.C., Gorwa, Vadodara 390 016 (INDIA)
Web: www.reckondiagnosics.com Ph: +91-265-2281631
Email: mail@reckondiagnosics.com
An ISO 13485:2016 & GMP Certified Company

 **RECKON**
DIAGNOSTICS P. LTD.
THE TEST OF CONFIDENCE - SINCE 1989