

LEPTOSPIRA CARD (IgG/IgM)

[Serum/Plasma]

IMMUNOPAK

Last update 10-2020

Ref. RDT-LPT.110, 10 Test

INTENDED USE

Leptospira (IgG/IgM) rapid test kit for IgG and IgM antibody against Leptospira interrogans

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 complexed 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 are captured by the immobilized anti-human antibodies. And then, the antibodies are reacted with L.interrogans-specific antigen-gold complex 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

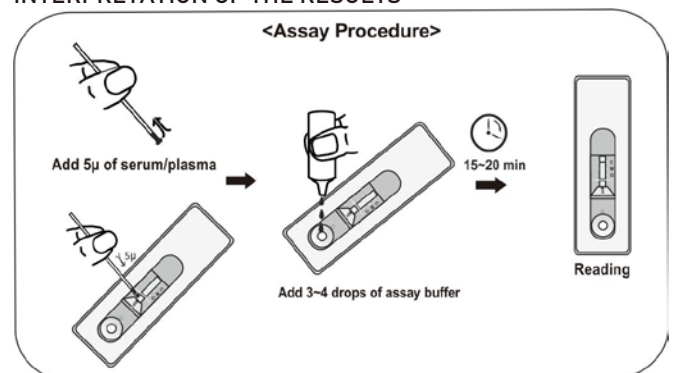
1. Specimen to be tested should be obtained and handled by standard methods for their collections.
 - **Serum:** allow the blood to clot, then centrifuge to separate the serum.
 - **Plasma:** collect the whole blood into the tube containing anticoagulants such as heparin, citrate, or EDTA. Centrifuge 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.

TEST PROCEDURE

1. Place all specimens, test devices, and Assay buffer and allow them to room temperature prior to testing (15-30min).
2. Using a sample dropper, add 5 μ l of serum/plasma into the sample well (S).
3. Add 3-4 drops (approx. 100 μ l) of assay buffer into the buffer well (B) in the device. And then, after 15-20 minutes, interpret the test results.

* Please do not read the results after 30 minutes of this testing.

INTERPRETATION OF THE RESULTS



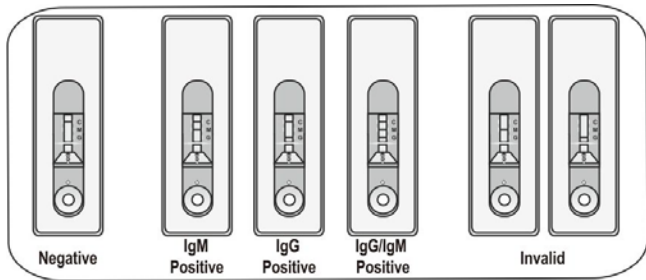
- **Negative:** Only one pink-purple line in the control line (C). No L.interrogans specific IgG and IgM were detected.
- **IgM Positive:** Two pink-purple lines are appeared in the IgM line (M) and control line (C). This is positive for IgM antibodies to L.interrogans and indicative of an acute L.interrogans 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.

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PERFORMANCE CHARACTERISTICS OF THE TEST

Reckon Leptospira IgG/IgM give 98.1% of overall sensitivity and 99.1% of overall specificity in the field trials shown as the below table. The kit has compared and analyzed with the reference tests including MAT (microscopic agglutination tests) and ELISA (enzyme-linked immunosorbent assay).

Reference Method	Reckon Leptospira IgG/IgM					Total
	Result	IgG Positive	IgM Positive	IgG Negative	IgM Negative	
ELISA /MAT	IgG Positive	56	0	1	0	57
	IgM Positive	0	48	0	1	49
	Negative	1	1	228	228	230
Total		59	50	228	229	236

Sensitivity= 98.2% [56/57] for IgG and 98.0% [48/49] for IgM
Specificity= 99.1% [228/230] for IgG and 99.1% [228/230] for IgM

LIMITATIONS OF THE TEST

Leptospira IgG/IgM is designed for primary screening test of *L.interrogans* infections. This kit can provide fast and easy way to get a result, but do not completely exclude the possibility of false positive or false negative result caused by various factors. So, refer to the result of this kit, please make a final decision with clinical manifestation, other test results, and doctor's view, collectively.

REFERENCES

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