PATHKITS

SIMPLE Leptospira IgG/IgM Test

Product Code: **PKRK034**
Kit Contents (**25 Kits**)
Shelf Life: 24 Months

Kit Components	Quantity (Units)
Test cassettes	25
Assay Buffer	1 Bottle
Sample Dropper	25
IFU	1

Introduction

Leptospirosis occurs worldwide and is a common mild to severe health problem for humans and animals, particularly in area with a hot and humid climate. 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* (1). The infection is spread via urine from the host animal. After infection, *leptospires* are present in the blood until they are cleared after 4 to 7 days following the production of *anti-Leptospira interrogans* antibodies, initially of the IgM class (2). Culture of the blood, urine and cerebrospinal fluid is an effective means of confirming the diagnosis during 1st to 2nd weeks after exposure. Serological detection of *anti- Leptospira* interrogans antibodies is also a common diagnostic method (3).

Intended Use

Simple Leptospira is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to *Leptospira interrogans* in human whole blood, serum or plasma.

Test Principle

Simple Leptospira IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a colored conjugate pad containing *L. interrogans* antigens conjugated with colloidal gold (Leptospira conjugates) and a control antibody conjugated with colloidal gold, 2) a nitrocellulose membrane strip containing two test lines (IgM and IgG lines) and a control line (C line). The IgM line is pre-coated with monoclonal anti human IgM for the detection of anti-*L. interrogans* IgM, and IgG line is pre-coated with monoclonal anti-human IgG for the detection of anti-*L. interrogans* IgG, and the C line is pre-coated with a control line antibody. 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 results.

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 a anti-L. interrogans IgG positive test result.

Warnings and Precautions

1. Read these instructions for use completely before performing the test. Failure to follow the instructions could lead to inaccurate test results.
2. Do not open the sealed pouch unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolyzed blood specimens for testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
10. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
11. Handle the negative and positive controls in the same manner as patient specimens.
12. The test results should be read 15-20 minutes after a specimen is applied to the sample well of the device. Any results interpreted outside of the 15–20-minute window should be considered invalid and must be repeated.
13. Do not perform the test in a room with strong air flow, i.e., an electric fan or strong air-conditioning.

Reagent Preparation and Storage Instructions

All reagents are ready to use as supplied. Store unused test devices unopened at 2-40°C. If stored at 2-8°C, ensure that the test device is brought to room temperature (15-30°C) before opening. The test device is stable through the expiration date printed on the pouch. Do not freeze or expose the kit to temperatures above 40°C.

Sample collection and Handling

1. Blood samples collected with a suitable anticoagulant such as EDTA or Heparin or Oxalate can also be used.
2. No prior preparation of the patient is required before sample collection by approved techniques.
3. Fresh serum / plasma is preferable. Anticoagulated whole blood can also be used as a specimen. Serum / plasma may be stored at 2- 8°C up to 24 hours in case of delay in testing.
4. Whole blood should be used immediately and should not be frozen.

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5. Repeated freezing and thawing of the specimen should be avoided.
6. Do not use hemolyzed, clotted, contaminated, viscous/turbid specimens..
7. Specimens containing precipitates or particulate matter must be centrifuged and the clear supernatant only should be used for testing.
8. For each sample, a new sample applicator should be used.

Materials Required but not provided

1. Timer or Stopwatch.
2. PPE and other consumables for collection and disposal of samples.

Limitations

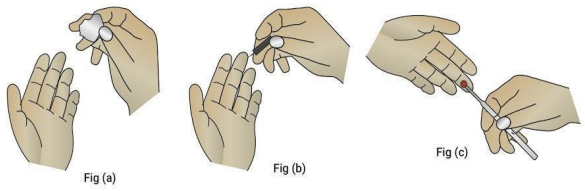
1. The Assay Procedure and the Interpretation Assay Result sections must be followed closely when testing for the presence of IgG and IgM antibodies to pathogenic *L. interrogans* in human serum/plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The Simple Leptospira IgG/IgM Rapid Test is limited to the qualitative detection of IgG and IgM antibodies to *L. interrogans* in human serum/plasma or whole blood. The intensity of the test line does not have a linear correlation with antibody titer in the specimen.
3. A negative result for an individual subject indicates absence of detectable anti-*L. interrogans* antibodies. However, a negative test result does not preclude the possibility of exposure to *L. interrogans.*
4. A negative result can occur if the quantity of anti-*L. interrogans* IgG and IgM antibodies present in the specimen are below the detection limits of the assay or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
5. Infection may progress rapidly. If the symptom persists, while the result from Simple Leptospira IgG/IgM Rapid Test is negative or non-reactive, it is recommended to test with an alternative test method.
6. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factors may affect expected results.
7. Depending on the circulating Leptospira serovars regionally present at the time of collection, sensitivity of this product may vary.
8. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

Test Procedure

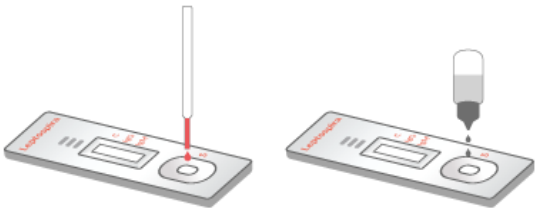
1. Bring the Simple Leptospira kit components to room temperature before testing.
2. Open the pouch and retrieve the device, sample applicator and desiccant pouch. Check the color of the desiccant. It should be blue, if it has turned colorless or pink, discard the device and use another device. Once opened, the device must be used immediately.
3. Add 10µl of serum/plasma or whole blood with a micropipette into the sample well.
4. Immediately dispense 2 drops of sample running buffer in the well by holding the plastic dropper bottle vertically.

Finger Prick Sample Collection:

- Clean the patient's fingertip with the alcohol or spirit. Wait until the finger has completely dried.
- Prick the patient's finger with the lancet, perpendicular to the lines of the finger print. Make sure a well-formed drop of blood is present on the tip of the finger.



- Take the sample dropper and collect 10µl of blood by dipping the tip of the sample dropper into the blood drop and immediately place the tip of the sample dropper in the sample well. Press the tip of the dropper onto the sample pad in the sample well to ensure that the complete volume of whole blood has been transferred to the strip.



- Immediately dispense 2 drops of sample running buffer into the well.
- Allow the reaction to occur for 15 minutes.
- Observe the results in 15 minutes. Do not read the result after 20 minutes. Reading beyond prescribed time may give false results.
- Discard the test card immediately after reading the results at 20 minutes.

Interpretation of results

Positive Results

(Please refer to the illustration below.)

- **IgG POSITIVE:** In addition to the presence of the C line, if only the IgG line develops, the test indicates the presence of anti-*L. interrogans* IgG. The result is *anti-L. interrogans* IgG positive or reactive.

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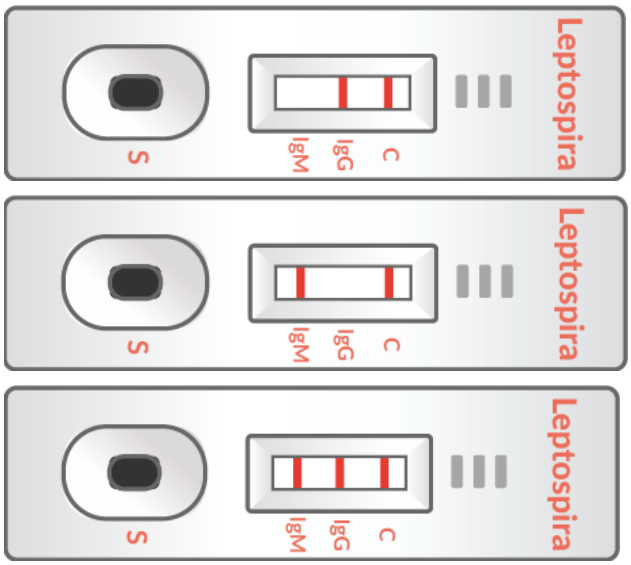
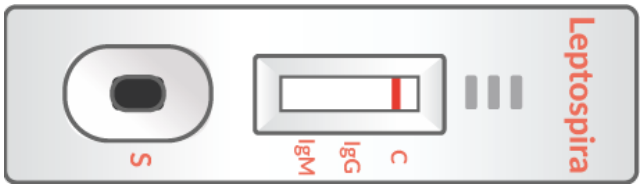
SIMPLE Leptospira IgG/IgM Test

- **IgM POSITIVE:** In addition to the presence of the C line, if only the IgM line develops, the test indicates the presence of anti-L. *interrogans* IgM. The result is *anti-L. interrogans* IgM positive or reactive.
- **IgG and IgM POSITIVE:** In addition to the presence of the C line, both the IgM and the IgG lines develop, the test indicates the presence of both *anti-L. interrogans* IgG and IgM. The result is both anti-L. interrogans IgG and IgM positive or reactive.



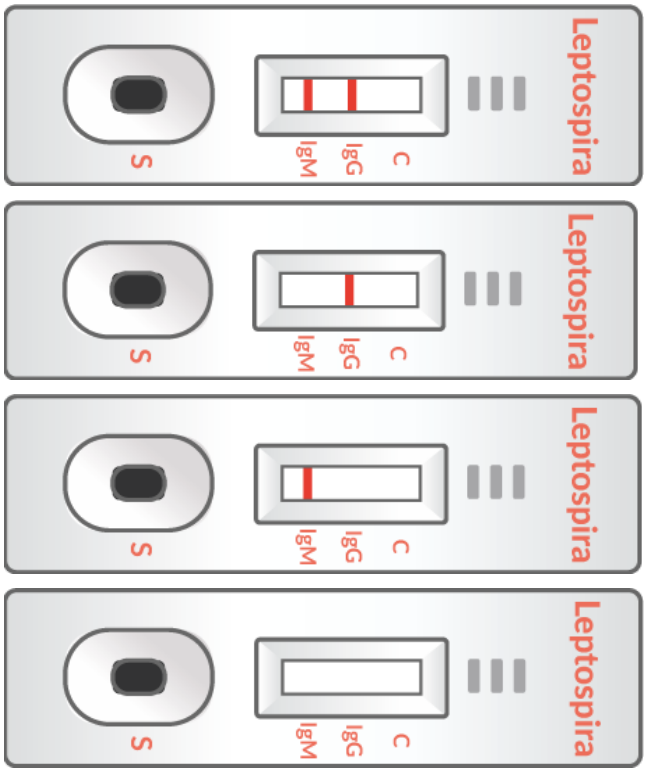
NOTE: Specimens with positive or reactive results should be confirmed with alternative testing method(s) and clinical findings before a diagnosis is made.

Negative Result: If only the C line is present, the absence of any color in both test lines (IgM and IgG) indicates that no detectable anti-*L. interrogans* antibody is present in the specimen. The result is negative or non-reactive.



Invalid Results

Control line does not appear in the Control (C) region. If no C line develops, the assay is invalid regardless of color development on the T line(IgG/IgM). Repeat the assay with a new device. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



Quality Control

Internal procedural controls are included in the test. A color line appearing in the control region (C) is an internal positive 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.

References

1. Marshall, R.B., 1992. International Committee on Systematic Bacteriology, Subcommittee on the Taxonomy of Leptospira. Minutes of the meeting. 13 and 15 September 1990, Osaka, Japan. *Int J Syst Bacteriol*, *42*, pp.330-334.
2. Johnson, R.C. and Faine, S., 1984. Leptospira. *Bergey's manual of systematic bacteriology*, *1*, pp.62-67.
3. Budihal, S.V. and Perwez, K., 2014. Leptospirosis diagnosis: competancy of various laboratory tests. *Journal of clinical and diagnostic research: JCDR*, *8*(1), p.199.

Technical Assistance

For customer support, please contact our Technical Support:

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Food and Drugs Administration Haryana
SCO-94, SEC-5, Panchkula

From

State Drugs Controller-cum-Licensing Authority
Food and Drugs Administration, Haryana,
SCO-94, Sector-5, Panchkula.

To

M/s Pathkits Healthcare Pvt, Ltd.,
Plot no. 28, 29, Sector-18,
Gurgaon, Haryana

Dated: 15-03-2022

Subject: Regarding additional items.

With reference to your application no. MFG/IVD/2022/55558 dated 23.02.2022 on the subject cited above.

Find enclosed herewith copy of Form MD-5, Lic No MFG/IVD/2021/000069 ,Endorsement No 05.

State Drugs Controller Haryana

सत्यमेव जयते

FORM MD-5

[See sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

Licence Number: MFG/IVD/2021/000069

Endorsement No. 5

1. M/s PATHKITS HEALTHCARE PRIVATE LIMITED, Plot No-28-29, Sector-18Gurgaon, Gurgaon, Haryana (India) - 122001 Telephone No.: 8802872273 FAX: 8802872273 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s PATHKITS HEALTHCARE PRIVATE LIMITED, PLOT NO. 28, 29, SECTOR-18, Gurgaon, Haryana (India) - 122001 Telephone No.: 8802872273 FAX: 8802872273

2. Details of medical device(s) [Annexed]

3. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
1	Generic Name:Leptospira Antibody (IgG/IgM) Test Kit Model No.:NIL Intended Use:It is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to leptospira interrogans in human whole blood, serum or plasma Class of medical device:Class B Material of construction:NA Dimension(if any):NA Shelflife:24 Months Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):SIMPLE Leptospira Antibody (IgG/IgM) Test Kit

Digitally signed by Manmohan Taneja
Date: 2022.03.15 16:34:48

Place:

Date:15-Mar-22

State Licensing Authority