OXALIS
Diagnostics Pvt. Ltd.

Rapichek

Rapid Leptospira IgG/IgM Antibody Test (Device)

For In-Vitro Diagnostic Use Only. Store at 4°C to 30°C

INTENDED USE

Rapid Leptospira IgG/IgM Antibody test is a lateral flow chromatographic immunoassay for the qualitative detection of Antibodies (IgG & IgM) specific to Leptospira interrogens (L.interrogens) in human serum, plasma or whole blood.It is intended to be used by healthcare professionals to aid in the diagnosis of infection with the Leptospira interrogens (L.interrogens). Alternative test method(s) should be considered to confirm the test result obtained by this device.

PRINCIPLE

After addition of the serum, plasma or whole blood sample to the sample well, add two drops of buffer solution into the same well of the device containing a test strip, If the Sample contains detectable level of leptospira interrogens (L.interrogens) IgM & IgG it reacts with gold conjugated leptospira IgM & IgG to form complex. This complex along with unbound Antibodies moves further on Nitrocellulose Membrane. This complex reacts with the IgM & IgG lines separately coated on Nitrocellulose Membrane. The unbound complex, unbound gold conjugate particles move further to control line coated on Nitrocellulose Membrane to form colour band. The appearance of test line and control line in respective area indicates the positive result. The appearance of test line IgM and control line C in respective area indicates IgM positive result. The appearance of test line IgG and control line C in respective area indicates IgG positive result. The appearance of test line IgM & IgG and control line C in respective area indicates IgM & IgG positive result. The appearance of only control line indicates a negative result. The control line acts as a procedural control. Control line should always appear if the test is performed as per the procedure and reagents are working properly.

CONTENTS OF KIT

1. Cassette
2. Silica Gel Pouch
3. Plastic Dropper (25µl)
4. Assay Buffer Bottle
5. Package Insert

OPTIONAL MATERIAL REQUIRED

1. Timer
2. Disposable gloves

STORAGE AND SATBILITY

Store in the sealed pouch in between 4°C to 30°C. Material provided are stable up to the expiration date printed on pouch/kit. DO NOT FREEZE, KEEP AWAY FROM DIRECT SUNLIGHT.

WARNINGS AND PRECAUTIONS

1. Please read the instruction carefully before performing the test.
2. For In Vitro Diagnostic use only.
3. Do not reuse the test.
4. Do not use the test after the expiration date.
5. Do not use cassette if cassette pouch is torn or damaged.
6. Use appropriate Personal Protective Equipment. Avoid direct skin contact.
7. Immediately carry out the test after removing the test device from the pouch.

WARNINGS AND PRECAUTIONS

8. Do not eat the Silica Gel Pouch in the package.
9. Do not mix or interchange the specimen sample.
10. Handle all specimen as if potentially infectious. Follow Standard Biosafety Guidelines during handling and disposal of materials to avoid the risk of infections.
11. The manufacturer and distributor of this product shall not be liable for any loses, liability, claims, costs or damages whether direct or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product

SPECIMEN COLLECTION

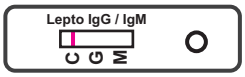
1. No special preparation of the patient is necessary prior to specimen collection by approved techniques.
2. BLOOD SPECIMENS : For Whole Blood, collect blood into suitable anti-coagulant tube (EDTA, Heparin, or Oxalate) and use the freshly collected blood.
3. PLASMA SPECIMEN: Collect blood into suitable anti-coagulant tube (EDTA, Heparin or Oxalate) and centrifuged the tube to obtain plasma specimen.
4. SERUM SPECIMEN: Collect the venous whole blood in the commercially available plain tube, not containing any anti-coagulant as mention above and leave to settle about 30 minutes for blood coagulation and then centrifuge to obtain serum specimen.
5. Repeated freezing and thawing of specimen should be avoided.
6. Do not use hemolyzed, clotted, contaminated, viscous/turbid specimen.
7. Refrigerated specimen must be brought to room temperature before testing.
8. Testing should be performed as early as possible after Collection. Do not leave Serum/Plasma/Whole blood at room temperature for prolonged periods.

TEST PROCEDURE

1. Allow the test and sample to reach room temperature (20°C to 30°C) before opening the foil pouch.
2. Remove the Cassette, Silica Gel pouch, and plastic dropper from the pouch. Check the Silica Gel pouch color, it should be blue. If it has turned colorless or pink, discard the test and use another test. Once open the device must be used immediately.
3. Label the device with specimen identity.
4. Add one drop (Approx 20-25µl) of serum or plasma sample. to the sample in well 'S', add two drops (Approx 70-80µl) of buffer solution into the same well in Leptospira IgG/IgM device.
5. Start the timer.
6. Read the result at 15 minutes. Do not read the result after 20 minutes.

INTERPRETATION OF RESULTS

Negative : Only one colored line appears at the control region 'C' only



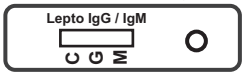
Positive : A) A distinct colored line appears at the control region 'C' and at the test region 'IgG' and 'IgM'.

B) A distinct colored line appears at the control region 'C' and at the test region 'IgM'

C) A distinct colored line appears at the control region 'C' and at the test region 'IgG'

Invalid: The test should be considered invalid if,

A) no line appears at 'C' region, 'IgG' and 'IgM' region



B)No line appears at 'C' region and line appear at 'IgM' and 'IgG' region

C)No line appears at 'C' and at 'IgM' region and line appear at 'IgG' region

D)No line appears at 'C' and at 'IgG' region and line appear at 'IgM' region

NOTE: The intensity of the color of test lines will vary depending upon the antibodies present in specimen.

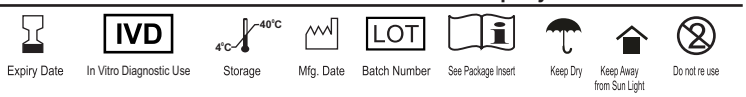
LIMITATIONS

- The Leptospira Antibody test is only for in-vitro diagnostic use.
- The Test device 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.
- 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.
- A negative result can occur if the quantity of anti-L. interrogans IgG and IgM 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 in which a sample is collected.
- Depending on the circulating Leptospira serovars regionally present at the time of collection, sensitivity of this product may vary.

OXALIS Diagnostics Pvt. Ltd.

Mfg.By : **OXALIS DIAGNOSTICS PVT.LTD.**
Plot No. D - 76, Five Star MIDC Area,Kagal,Dist.Kolhapur - 416216(MS) India.
Customer Care No. : 0231-2305072
Email : oxalispvtltd@outlook.com

An ISO 13485:2016 and ISO 9001:2015 Certified Company



Expiry Date | In Vitro Diagnostic Use | Storage | Mfg. Date | Batch Number | See Package Insert | Keep Dry | Keep Away from Sun Light | Do not re use

PATHOZYME DIAGNOSTICS

Rapichek

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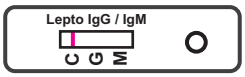

Positive : A) A distinct colored line appears at the control region 'C' and at the test region 'IgG' and 'IgM'.

B) A distinct colored line appears at the control region 'C' and at the test region 'IgM'

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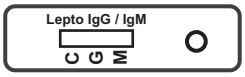

B)No line appears at 'C' region and line appear at 'IgM' and 'IgG' region

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PATHOZYME DIAGNOSTICS

Mfg.By : **PATHOZYME DIAGNOSTICS**
Plot No. A - 115, Five Star MIDC Area,Kagal,Dist.Kolhapur - 416216(MS) India.
Customer Care No. : 0231-2305072
Email : contactus@pathozyme.com

An ISO 13485:2016 and ISO 9001:2015 Certified Company

Expiry Date | IVD In Vitro Diagnostic Use | 4°C 40°C Storage | Mfg. Date | LOT Batch Number | See Package Insert | Keep Dry | Keep Away from Sun Light | Do not re use