ImmunoScience INDIA

ImmunoQuick

Leptospira IgM

Rapid test for detection of IgM antibodies to Leptospira – Device

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

OVERVIEW

Leptospirosis is a disease caused by the bacteria Leptospira. Humans can get leptospirosis through direct contact with urine from infected animals or through water, soil or food contaminated with their urine. It's most common in warm climates. High fever, headache, bleeding, muscle pain, chills, red eyes and vomiting are some symptoms. Without treatment, leptospirosis can lead to kidney and liver damage and even death. Antibiotics treatment can cure the infection. Hence, the timely diagnosis plays an important role to control it.

INTENDED USE

Rapid test for detection of IgM antibodies to Leptospira is an immunochromatographic assay for the qualitative Detection of Leptospira specific IgM antibodies in human serum/plasma or whole blood.

PRINCIPLE

After addition of the serum or plasma and the assay buffer to the sample well of the device containing a test strip, the sample moves on to the conjugate pad containing colloidal gold particles conjugated with human IgM specific antibodies and streptavidin. If the sample contains detectable levels of the Leptospira specific IgM antibodies, it reacts with the gold conjugated human IgM specific antibodies to form a complex. This complex moves further reacts with recombinant Leptospira antigen test line coated on the nitrocellulose membrane area to form colored band. The unbound complex and the Streptavidin conjugated colloidal gold particles move further to the Biotin coated control area to form a colored band (Control line). The appearance of test line/s and control line in respective area indicates the positive result. 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. Test device with desiccant and dropper
2. Assay Buffer
3. Package Insert

OPTIONAL MATERIAL REQUIRED

1. Timer
2. Sample container
3. Micro pipette
4. Disposable Gloves

PRECAUTIONS/KIT STORAGE AND STABILITY

1. Please read all the information in this package insert before performing the test. Pay particular attention to the position of the Control and Test lines.
2. Do not use after the expiration date printed on the foil pouch.
3. Store in the sealed pouch in a dry place in between temperature 4°C to 30°C. Do not freeze.
4. Do not use if pouch is torn or damaged.
5. Do not open the foil pouch until you are ready to start the test.
6. Keep out of the reach of children.

WARNINGS

1. Do not reuse the test device.
2. Follow the instruction to get accurate results.
3. Use appropriate personal protective equipment.
4. Dispose off hygienically in Biohazard waste.
5. Do not touch the membrane.
6. Treat samples and used test as potentially infectious. Avoid contact with skin.
7. For in vitro diagnostic use. Not to be taken internally.
8. Do not eat the desiccant in the package.
9. Do not mix the specimen sample or interchange the different specimen.

SPECIMEN COLLECTION

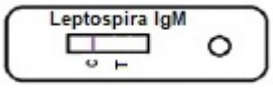
1. Testing should be performed using fresh serum, plasma or whole blood.
2. Do not leave serum/Plasma at room temperature for prolonged periods.
3. Use K2, K3 EDTA blood collection tubes for whole blood or plasma collection.
4. Use plain blood collection tubes for serum sample collection. Allow the plain sample to clot and settle down to remove serum supernatant. Plasma can be separated by centrifuge the EDTA sample and collecting supernatant.

TEST PROCEDURE

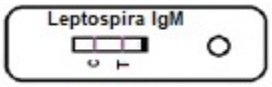
1. Allow the test device and sample reach to room temperature (20°C to 30°C) before opening the foil pouch.
2. Remove the test device, desiccant and plastic dropper from the pouch. The color of desiccant shall be blue. Do not use the device if the desiccant is colorless or pink.
3. Use the test device as early as possible after opening the pouch
4. Label the device with sample identity.
5. Put the device on plain surface and add 10 µl of serum / plasma or 20 µl whole blood sample in sample well and add 2 drops (Approx. 60 µl) of assay buffer in sample well.
6. Start the timer.
7. 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

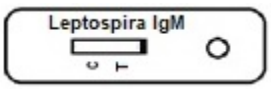


Positive: A) A distinct colored line appears at the control region 'C' and at the test region 'T'.

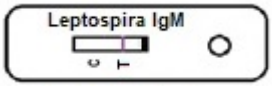


Invalid: The test should be considered invalid if,

A) no line appears at 'C' region, at the test region 'T'.



B) No line appears at 'C' region and line appear at the test region 'T'.



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

LIMITATIONS

1. As with all diagnostic tests, the test result must always be correlated with clinical findings.
2. The results of test are to be interpreted within the epidemiological, clinical and therapeutic context.
3. Any modification to the above procedure and / or use of other reagents will invalidate the test procedure.

DISCLAIMER

The all precaution shall be taken to ensure the diagnostic ability and accuracy of this product. This product is utilized outside the control of manufacturer and distributors. The various factors including storage temperature, environmental conditions and procedure error may affect the results. Hence, positive test needs to be confirmed by confirmatory tests.

PERFORMANCE CHARACTERISTICS

1. Total 185 samples are evaluated for specificity, sensitivity. sensitivity was found 100% (60/60) and relative specificity was 100% (125/125).
2. Hence, All the three lots demonstrated a sensitivity and specificity of 100 % in comparison with Reference comparator Rapid test kit.
3. The Positive predictive value (PPV) and Negative Predictive value (NPV) for the test was 100 %.
4. No cross reactivity found with HIV, HCV, H. Pylori, HBsAg and syphilis Ab positive samples.
5. Lowest detection limit is observed up to 1:128 titer of positive sample.

Sample	ImmunoQuick Lepto IgM		Reference		Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
	Positive	Negative	Positive	Negative				
Positive	60	0	60	0	100	-	100	-
Negative	0	100	0	100	-	100	-	100
Cross reactivity	0	25	0	25	No cross reactivity observed			
Total	60	125	60	100	-			

REFERENCES

1. International Multicentre Evaluation of the Clinical Utility of a Assay for Detection of Leptospira-specific Immunoglobulin M antibodies in Human Serum Specimens., Smits et al., Journal of Clinical Microbiology, Sept 1999, Vol. 37, No. 9, p. 2904-2909.
2. Gussenhoven et al., Journal of Clinical Microbiology, Jan 1997, Vol. 35, No.1, p. 92-97, LEPTO Dipstick, a Dipstick Assay for detection of Leptospira Specific Immunoglobulin M antibodies in Human Sera.,.
3. Two Methods for Rapid Serological Diagnosis of Acute Leptospirosis, Levett et al., Clinical and Diagnostic Laboratory Immunology, Mar 2001, Vol. 8, No. 2, p. 349-351.
4. Leptospirosis in Kuala Lumpur and the Comparative Evaluation of Two Rapid Commercial Diagnostic kits against the MAT test for the detection of antibodies to Leptospira interrogans., Sekhar et al., Singapore Med J 2000, Vol. 41 (8): 370-375.
5. An Evaluation of Three Rapid Commercial Screening tests for leptospiral antibodies., Tanvi Panwala et al., Journal of Clinical and Diagnostic Research 2015, Feb, Vol-9 (2) : DC21-DC24.

	In Vitro Diagnostic Use
	Manufacturer
	Manufacturing Date
	Expiry Date
	Lot Number
	Store at 4°C to 30°C
	Single Use
	Number of tests in the pack
	Do not use if pouch or kit damaged
	This side Up
	Read package insert before use