

ADVANTAGE

Leptospira IgM & IgG Card

Distinguish pathogenic Leptospira from other diseases

Rapid diagnostic test for the Qualitative detection of Leptospira specific IgM & IgG antibodies in human serum/ plasma

Lepto IgM Microlisa

Microwell ELISA Test for the Qualitative Detection of Leptospira Specific IgM antibody in Human Serum/Plasma



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J. Mitra & Co. Pvt. Ltd.

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Leptospira: An emerging disease

Leptospirosis is a disease caused by infection with bacteria of the genus *Leptospira* that affects human as well as other mammals. Though recognised among the world's most common diseases transmitted to people from animals, the infection is commonly transmitted to human by allowing water that has been contaminated by animal urine to come in contact with unhealed breaks in the skin, the eyes, or with the mucous membranes. Leptospirosis is a biphasic disease that begins with flu-like symptoms (fever, chills, myalgias, intense headache). The first phase resolves, and the patient is briefly asymptomatic until the second phase begins.

This is characterized by meningitis, liver damage (causing jaundice), and renal failure. The infection is often wrongly diagnosed due to the wide range of symptoms. This leads to a lower registered number of cases than exists. Symptoms of leptospirosis include high fever, severe headache, chills, muscle aches, and vomiting, and may include jaundice, red eyes, abdominal pain, diarrhea, and rash. Initial presentation may resemble pneumonia. The symptoms in human appear after 2-20 days incubation period

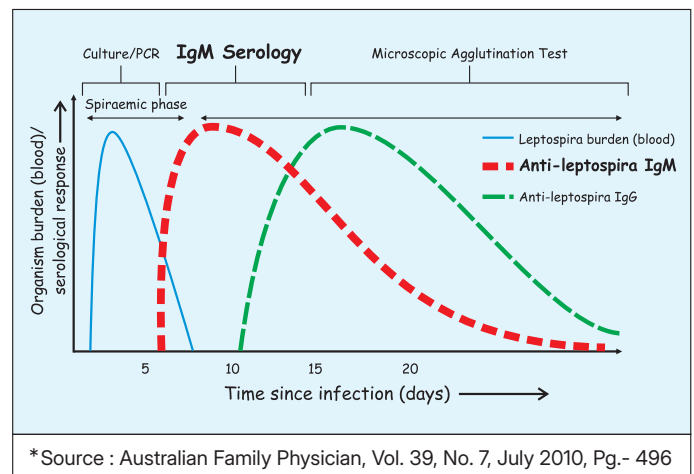
Prototypic antibody response in Leptospirosis against time*

Most cases of leptospirosis are diagnosed by serology as:-

Antibodies become detectable by 6th to 10th day of disease and generally reach peak levels within 3 to 4 weeks. The incubation period of 2-20 days is followed by a biphasic disease, with an acute spiraemic phase of approximately 7 days followed by an immunogenic phase characterized by the production of IgM and later IgG Antibodies.

IgM Antibodies are detectable in sera within 6 to 10 days after infection followed by IgG Antibodies.

Other tests like Culture/PCR are not an optimal tool to determine the initiation of management of disease due to 1-2 week delay in definitive diagnosis and the diagnosis varies based on infecting serovar of *Leptospira*.



ADVANTAGE

Leptospira IgM & IgG Card

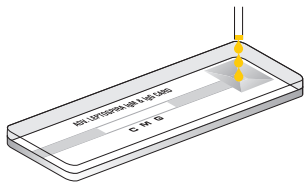
Salient Features

- One Step procedure, add sample & read Result
- Bio-hazard free, fully covered, see-through Device
- Rapid, visual and qualitative immunoassay
- Results within 20 minutes
- Shelf life 30 months at 2-30°C
- Sensitivity: 99% & Specificity: 99.5%
- Convenient pack size of 10 test cards



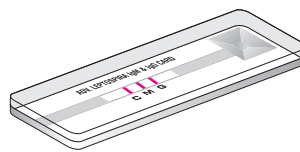
Test Procedure

STEP - 1



Add 3 drops (100 µl) of serum/ plasma sample using sample dropper into the sample well

STEP - 2

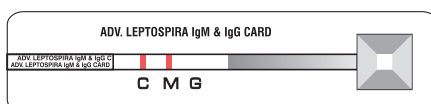


Allow reaction to occur during next 20 minutes and READ RESULTS

Result Interpretation



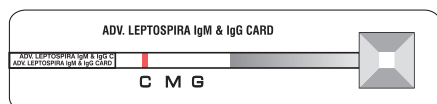
Reactive for both leptospira IgM & IgG antibodies



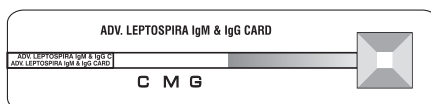
Reactive for leptospira IgM antibodies



Reactive for leptospira IgG antibodies



Non-Reactive for leptospira antibodies



Invalid Test & re-run the test

Lepto IgM Microlisa

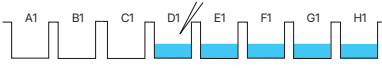
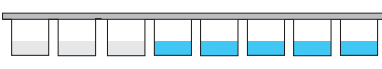
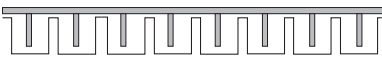
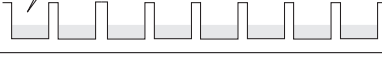
Salient Features

- Based on Indirect Elisa
- Easy to use on Automated & Semiautomated Processor
- Colour Coded reagents to monitor procedural steps
- Unique Break-away wells
- Assay procedure: 120 minutes
- Shelf Life : 24 Months at 2-8°C
- Excellent Sensitivity 100% and Specificity 99.97%
- Convenient pack size of 96 test cards

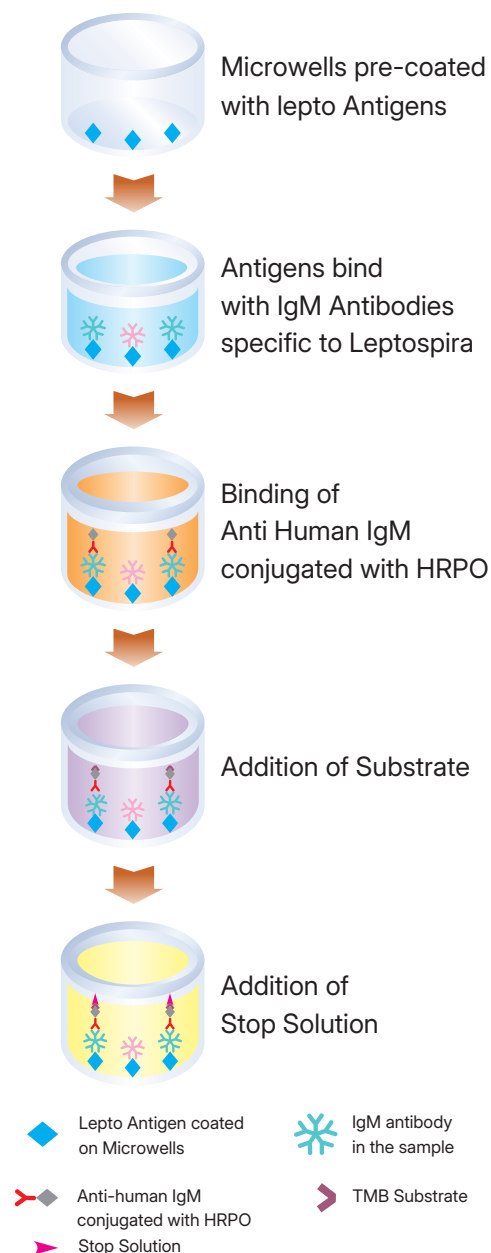


Lepto IgM Microlisa

Test Procedure

Treat serum/ plasma sample (1:11); Take sample 10 µl + RF Absorbent 100µl in a test tube & mix properly. Incubate for 10 min at RT.																																																					
Add 100 µl Sample Diluent in each well starting from D1.																																																					
Add 125 µl Negative Control in A1 & B1 well, 125 µl Positive Control in C1 well and 25 µl treated sample in respective wells from D1 well onwards.																																																					
Cover the plate and incubate for 30 min. at 37°C																																																					
Wash (5 cycles)																																																					
Prepare working conjugate solution (1:50)	<table><tr><td>No. of strip</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td><td>10</td><td>11</td><td>12</td></tr><tr><td>Enzyme conjugate</td><td>20</td><td>40</td><td>60</td><td>80</td><td>100</td><td>120</td><td>140</td><td>160</td><td>180</td><td>200</td><td>220</td><td>240</td></tr><tr><td>Concentrate (µl)</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td><td>10</td><td>11</td><td>12</td></tr><tr><td>Conjugate Diluent(ml)</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>	No. of strip	1	2	3	4	5	6	7	8	9	10	11	12	Enzyme conjugate	20	40	60	80	100	120	140	160	180	200	220	240	Concentrate (µl)	1	2	3	4	5	6	7	8	9	10	11	12	Conjugate Diluent(ml)												
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Add 100 µl working substrate in each well																																																					
Incubate in dark for 30 min at room temperature.																																																					
Add 50 µl Stop Solution and read result at 450 nm/630 nm.																																																					

Test Principle



Performance Characteristics

The kit has been evaluated with a known panel of Lepto IgM Negative & Positive samples and also the cross reacting samples.

Following are the results of in-house evaluation:

Sensitivity : 99.62% Specificity : 99.92%



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A 180-181, Okhla Indl. Area, Phase-1, New Delhi - 110 020, INDIA | Tel: +91-11-47130300, 47130500
E-mail: jmitra@jmitra.co.in | Website: www.jmitra.co.in

ISO 13485:2016
ICMED 13485