Leptospira IgG/IgM Rapid Test Cassette (WB/S/P)

English

For professional and in vitro diagnostic use only.

[INTENDED USE]

The Leptospira IgG/IgM Rapid Test Cassette is a lateral flow immunoassay for the qualitative detection of IgG and IgM antibodies to Leptospira interrogans (L. interrogans) in human whole blood, serum or plasma. It provides an aid in the diagnosis of infection with L. interrogans.

[SUMMARY]

The clinical manifestations of leptospirosis range from a mild catarrh like illness to icteric disease with servere liver and kidney involvement. The organisms occupy the lumen of nephritic tubules in their natural host and are shed in to the urine. Human infection derives from direct exposure to infected animals for e.g. (veteringarians, abattoir workers, of daity exposure to environment contaminated by animal carriers (e.g. agricultural workers). Bathing or swimming in water sources about which live stock have been pastured has been demonstrated to be a potential infection hazard. The organisms enter the host through skin abrasions, mucosal surfaces or the eye. The incubation period can range from 3 to 30 days but is usually found to be 10 to 12 days. Antibodies can become detectable by the 6th to 10th day of disease and generally reach peak levels within 3 to 4 weeks. Antibody levels then gradually recede but may remain detectable for years. One step Leptospira IgG/IgM Test is a simple, visual qualitative test that detects IgG and IgM antibodies to Leptospira interrogans in human whole blood, serum or plasma. The test is based on immunochromatography and can give a result within 15 minutes.

[PRINCIPLE]

The Leptospira IgG/IgM Rapid Test Cassette is a qualitative membrane strip based immunoassay for the detection of IgG and IgM antibodies to Leptospira interrogans in human whole blood, serum or plasma. The test cassette consists of: 1) a burgundy colored conjugate pad containing Leptospira recombinant specific antigens conjugated with colloid gold (Leptospira conjugates), 2) a nitrocellulose membrane strip containing two test lines (IgG and IgM lines) and a control line (C line). The IgG line is pre-coated with the antibody for the detection of IgG antibodies to Leptospira, IgM line is pre-coated with antibody for the detection of IgM antibodies to Leptospira. When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. IgM antibodies to Leptospira, if present in the specimen, will bind to the Leptospira conjugates. The immunocomplex is then captured by the reagent pre-coated on the IgM line, forming a burgundy colored IgM line, indicating a Leptospira IgM positive test result. IgG antibodies to Leptospira if present in the specimen will bind to the Leptospira conjugates. The immunocomplex is then captured by the reagent pre-coated on the IgG line, forming a burgundy colored IgG line, indicating a Leptospira IgG positive test result. Absence of both T lines (IgG and IgM) suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

[WARNINGS AND PRECAUTIONS]

- For *in vitro* diagnostic use only.
- For healthcare professionals and professionals at point of care sites.
- Do not use after the expiration date.
- Please read all the information in this leaflet before performing the test.
- The test cassette should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test cassette should be discarded according to federal, state and local regulations.

[COMPOSITION]

The test contains a membrane strip coated with Mouse anti-Human IgM antibody and Mouse anti-Human IgG antibody on the test line, Goat anti-Leptospira polyclonal antibody on the control line, and a dye pad which contains colloidal gold coupled with Leptospira recombinant antigens.
The quantity of tests was printed on the labeling.

Materials Provided

- Test cassette
- Package insert
- Buffer
- Dropper

Materials Required But Not Provided

- Specimen collection container
- Timer

[STORAGE AND STABILITY]

- Store as packaged in the sealed pouch at temperature (4-30℃ or 40-86℉). The kit is stable within the expiration date printed on the labeling.
- Once open the pouch, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.
- The LOT and the expiration date were printed on the labeling.

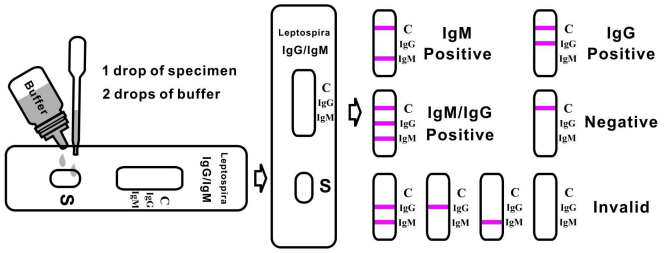
[SPECIMEN]

- The test can be used to test whole blood, serum or plasma specimens.
- To collect whole blood, serum or plasma specimens following regular clinical laboratory procedures.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- Store specimens at 2-8℃ (36-46℉) if not testing immediately. Store specimens at 2-8℃ up to 7 days. The specimens should be frozen at -20℃ (-4℉) for longer storage. Do not freeze whole blood specimens.
- Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.
- Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

[TEST PROCEDURE]

Allow the test device and specimens to equilibrate to temperature (15-30℃ or 59-86℉) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the test cassette on a clean and level surface.
3. Hold the dropper vertically and transfer 1 drop of specimen (approximately 35 µL) to the specimen well (S) of the test cassette, then add 2 drops of buffer (approximately 70 µL) and start the timer. See illustration below.
4. Wait for the colored line(s) to appear. Read results at 15 minutes. Do not interpret the result after 20 minutes.



(The picture is for reference only, please refer to the material object.)

[INTERPRETATION OF RESULTS]

Positive: Control line and at least one test line appear on the membrane. The appearance of IgM test line indicates the presence of Leptospira specific IgM antibodies. The appearance of IgG test line indicates the presence of Leptospira specific IgG antibodies. And if both IgG and IgM line appear, it indicates that the presence of both Leptospira specific IgG and IgM antibodies.
Negative: One colored line appears in the control region (C). No apparent colored line appears in the test line region.
Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

[QUALITY CONTROL]

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.
Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

[LIMITATIONS]

- The Leptospira IgG/IgM Rapid Test Cassette is limited to provide a qualitative detection. The intensity of the test line does not necessarily correlate to the concentration of the antibody in the blood.
- The results obtained from this test are intended to be an aid in diagnosis only. Each physician must interpret the results in conjunction with the patient's history, physical findings, and other diagnostic procedures.
- A negative test result indicates that antibodys to Leptospira are either not present or at levels undetectable by the test.

[PERFORMANCE CHARACTERISTICS]

Accuracy

A side-by-side comparison was conducted using the Leptospira IgG/IgM Rapid Test and commercially available Leptospira rapid tests. 1036 clinical specimens from three Professional Point of Care sites were evaluated with the Leptospira IgG/IgM Rapid Test and the commercial kit. The discrepant specimens were checked with a commercially available ELISA to confirm the presence of Leptospira IgG/IgM antibodies in the specimens. The following results are tabulated from these clinical studies:

Leptospira-IgG:

Agreement with Commercial Leptospira Rapid Test

Leptospira-IgG		Commercial Leptospira Rapid Test		Total
		Positive	Negative	
	Positive	356	7	363
	Negative	3	670	673
Total		359	677	1036

The agreement between these two devices is 99.16% for positive specimens, and 98.97% for negative specimens. This study demonstrated that the Leptospira IgG Rapid Test is substantially equivalent to the commercial device.

Agreement with ELISA

Leptospira-IgG		ELISA		Total
		Positive	Negative	
	Positive	355	8	363
	Negative	4	669	673
Total		359	677	1036

A statistical comparison was made between the results yielding a clinical sensitivity of 98.89%, a clinical specificity of 98.82% and an accuracy of 98.84%.

Leptospira-IgM:

Agreement with Commercial Leptospira Rapid Test

Leptospira-IgM		Commercial Leptospira Rapid Test		Total
		Positive	Negative	
	Positive	199	3	202
	Negative	3	831	834
Total		202	834	1036

The agreement between these two devices is 98.51% for positive specimens, and 99.64% for negative specimens. This study demonstrated that the Leptospira IgM Rapid Test is substantially equivalent to the commercial device.

Agreement with ELISA

Leptospira-IgM		ELISA		Total
		Positive	Negative	
	Positive	197	5	202
	Negative	5	829	834
Total		202	834	1036

A statistical comparison was made between the results yielding a clinical sensitivity of 97.52%, a clinical specificity of 99.40% and an accuracy of 99.03%.

Cross-Reactivity and Interference

1. Other common causative agents of infectious diseases were evaluated for cross-reactivity with the test. Some positive specimens of other common infectious diseases were spiked into the Leptospira positive and negative specimens and tested separately. No cross-reactivity was observed with specimens from patients infected with HIV, HAV, HBsAg, HCV, HTLV, CMV and TP.

2. Potentially cross-reactive endogenous substances including common serum components, such as lipids, hemoglobin and bilirubin, were spiked at high concentrations into the Leptospira positive and negative specimens and tested, separately. No cross-reactivity or interference was observed to the device.

Analytes	Conc.	Specimens	
		Positive	Negative
Albumin	20 mg/mL	+	-
Bilirubin	20 µg/mL	+	-
Hemoglobin	15 mg/mL	+	-
Glucose	20 mg/mL	+	-
Uric Acid	200 µg/mL	+	-
Lipids	20 mg/mL	+	-

3. Some other common biological analytes were spiked into the Leptospira positive and negative specimens and tested separately. No significant interference was observed at the levels listed in the table below.

Analytes	Conc.	Specimens	
		Positive	Negative
Acetaminophen	200 µg/mL	+	-
Acetoacetic Acid	200 µg/mL	+	-
Acetylsalicylic Acid	200 µg/mL	+	-
Benzoylecgonine	100 µg/mL	+	-
Caffeine	200 µg/mL	+	-
EDTA	800 µg/mL	+	-
Ethanol	1.0%	+	-
Gentisic Acid	200 µg/mL	+	-
β - Hydroxybutyrate	20,000 µg/mL	+	-
Methanol	10.0%	+	-
Phenothiazine	200 µg/mL	+	-
Phenylpropanolamine	200 µg/mL	+	-
Salicylic Acid	200 µg/mL	+	-

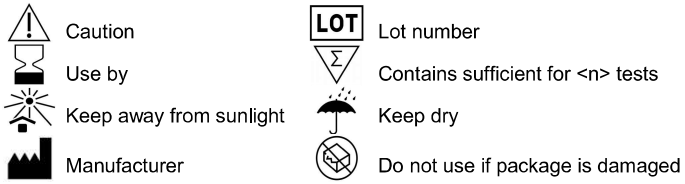
Reproducibility

Reproducibility studies were performed for Leptospira IgG/IgM Rapid Test at three physician office laboratories (POL). Sixty (60) clinical serum specimens, 20 negative, 20 borderline positive and 20 positive, were used in this study. Each specimen was run in triplicate for three days at each POL. The intra-assay agreements were 100%. The inter-site agreement was 100%.

[BIBLIOGRAPHY]

1. Bharti AR, Nally JE, Ricaldi JN, Matthias MA, Diaz MM, Lovett MA, Levett PN, Gilman RH, Willig MR, Gotuzzo E, Vinetz JM. Leptospirosis, a zoonotic disease of global importance. The Lancet infectious diseases 2003;3 (12): 757–71.
2. Stimson AM, Note on an organism found in yellow-fever tissue. Public Health Reports1907 ;22: 541.
3. leptospirosis. American Heritage Dictionary of the English Language: Fourth Edition. Bartleby.com. 2000. Retrieved 2007-05-13.

Index of Symbol



Version No.: 2.0
Effective Date: Jul. 30, 2018