SD BIO LINE LEPTOSPIRA IgM

1. Explanation of the test

[INTRODUCTION]

Leptospirosis is a bacterial disease that affects humans and animals. It is caused by bacteria of the genus Leptospira. In humans it causes a wide range of symptoms, and some infected persons may have no symptoms at all. Symptoms of leptospirosis include high fever, severe headache, chills, muscle aches, and vomiting, and may include jaundice (yellow skin and eyes), red eyes, abdominal pain, diarrhea, or a rash. If the disease is not treated, the patient could develop kidney damage, meningitis (inflammation of the membrane around the brain and spinal cord), liver failure, and respiratory distress. In rare cases death occurs. Many of these symptoms can be mistaken for other diseases. Leptospirosis is confirmed by laboratory testing of a blood or urine sample.

Leptospirosis occurs worldwide but is most common in temperate or tropical climates. It is an occupational hazard for many people who work outdoors or with animals, for example, farmers, sewer workers, veterinarians, fish workers, dairy farmers, or military personnel. It is a recreational hazard for campers or those who participate in outdoor sports in contaminated areas and has been associated with swimming, wading, and whitewater rafting in contaminated lakes and rivers. The incidence is also increasing among urban children.

[INTENDED USE]

The SD BIOLINE LEPTOSPIRA IgM Test is a solid phase immunochromatographic assay for the rapid, qualitative detection of IgM antibody to *Leptospira interrogans* in human serum, plasma or whole blood. This test is intended for professional use as an aid in the clinical laboratory diagnosis of patients with clinical symptoms consistent with leptospirosis. This test provides only a preliminary test result. Therefore, other serological test like MAT reference test, ELISA, PHA must be used in order to obtain a confirmation of *Leptospira interrogans* infection.

[PRINCIPLE]

The SD BIOLINE LEPTOSPIRA IgM Test has 2 pre-coated lines, "T" (*Leptospira interrogans* IgM Test Line), and "C" (Control Line) on the surface of the strip. These lines in result window are not visible before applying any samples. The "Control Line" is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working. A purple "T" line will be visible in the result window if there are enough IgM antibody to *Leptospira interrogans* in the sample. If IgM antibody to *Leptospira interrogans* are not present in the sample, there is no color appears in "T".

2. Materials provided

1) Test devices individually foil pouched with a desiccant
2) Assay diluent
3) Instruction for use

3. Precaution / kit storage and stability

1) The SD BIOLINE LEPTOSPIRA IgM Test should be stored at room temper ature (1 ~ 30℃) The test device is sensitive to humidity and as well as to heat.
3) Perform the test immediately after removing the test device from the container.
4) Do not use it beyond the expiration.
5) DO NOT FREEZE.
6) Do not store the test kit in direct sunlight.

4. Specimen collection, storage and precaution

1) Whole blood

(1) Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture.
(2) If blood specimens are not immediately tested, they should be refrigerated at 2~8℃.
(3) When stored at 2~8℃, the blood specimens should be used within 3 days.
(4) For storage period longer than 3 days, freezing is recommended. They should be brought to room temperature (1~30℃) prior to use.
(5) Using the blood specimens in the long-term keeping more than 3 days can cause non-specific reaction.

2) Plasma or Serum

(1) [Plasma] Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture and then centrifuge blood to get plasma specimen.
(2) [Serum] Collect the whole blood into the collection tube (not containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
(3) If plasma or serum specimens are not tested immediately, they should be refrigerated at 2~8℃. For storage period longer than 2 weeks, freezing is recommended. They should be brought to room temperature (1~30℃) prior to use.
(4) Plasma or serum specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

5. Warnings

1) For in vitro diagnostic use only.
2) Do not eat or smoke while handling specimens.
3) Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
4) Clean up spills thoroughly using an appropriate disinfectant.
5) Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
6) Do not use the test kit if the pouch is damaged or the seal is broken.
7) Specimens and all materials coming into contact with should be handles and disposed of as though potentially infectious.

6. Procedure of the test

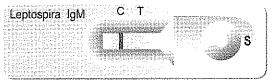
1) Allow all kit components and specimen to room temperature (1 ~ 30℃) prior to testing.
2) Remove the test device from the foil pouch, and place it on a flat, dry surface.
3) Slowly add 10㎕ of serum, plasma (or 20㎕ of whole blood) to the sample well and then add 3 ~ 4 drops of the assay diluent.
4) As the test begins to work, you will see purple color move across the result window in the center of the test device.
5) Interpret test results at 15 ~ 20 minutes.

7. Interpretation of the test

A color band will appear in the left section of the result window to show that the test is working properly. This band is the control band. The right section of the result window indicates the test results. If another color band appears in the right section of the result window. This band is the test band.

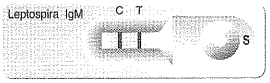
1) Negative Result

The presence of only control band ("C") within the result window indicates a negative result.



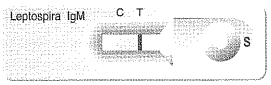
2) Positive Result

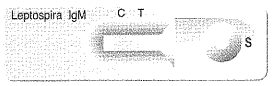
The presence of two color bands ("T" and "C") within the result window, no matter which band appears first indicates a positive result.



3) Invalid Result

If the control band is not visible within the result window after performing the test, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.





8. Limitations of the test

1) This test detects the presence of IgM antibodies to *Leptospira interrogans* in the specimen and should not be used as the sole criterion for the diagnosis of leptospirosis.
2) As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
3) If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. Also a negative results does not preclude the possibility of an infection of *Leptospira interrogans*.

9. Performance Characteristics

1) Sensitivity and Specificity

The SD BIOLINE LEPTOSPIRA IgM test have tested with positive and negative clinical samples tested by a leading commertial PHA kit. We used clinical positive and negative Specimans Confirmed by MAT.

Table 1. Serological Sensitivity and Specificity of the SD BIOLINE LEPTOSPIRA IgM

Sera Characterisation	SD BIOLINE LEPTOSPIRA IgM			A Commertial PHA		
	Positive	Negative	Total	Positive	Negative	Total
Seropositive (+)	53	2	55	52	3	55
Seronegative (-)	7	143	150	8	142	150
Total	60	145	205	60	145	205

In this studies, SD BIOLINE LEPTOSPIRA IgM test gave Sensitivity of 96.3% (53/55), Specificity of 95.3% (143/150) and a Serological Agreement of 95.6% (196/205) with MAT.

2) Precision

(1) Within run precision was determined by using 10 replicates of four different specimens containing different concentrations of antibody. The negative and positive values were correctly identified 100% of the time.
(2) Between run precision was determined by using the four different specimens containing different concentrations of antibody in 3 different replicates with 3 different lots of test devices. Again negative and positive results were observed 100% of the time.

10. Bibliography of suggested reading

1) Mulla S, Chakraborty T, Patel M, Pandya HP, Dadhaniya V, Vaghela G., Diagnosis of leptospirosis and comparison of ELISA and MAT techniques., Indian J Pathol Microbiol. 2006 Jul;49(3):468-70.
2) Bajani MD, Ashford DA, Bragg SL, Woods CW, Aye T, Spiegel RA, Plikaytis BD, Perkins BA, Phelan M, Levett PN, Weyant RS., Evaluation of four commercially available rapid serologic tests for diagnosis of leptospirosis., J Clin Microbiol. 2003 Feb;41(2):803-9.
3) Camargo ED, da Silva MV, Batista L, Vaz AJ, Sakata EE.., [An evaluation of the ELISA-IgM test in the early diagnosis of human leptospirosis], Rev Inst Med Trop Sao Paulo. 1992 Jul-Aug;34(4):355-7. Portuguese.

Date Issued : 2007. 11
16FK30-02-1

SD STANDARD DIAGNOSTICS, INC.
156-68 Hagal-dong, Giheung-gu, Yongin-si, Kyonggi-do, Korea
Tel : 82-31-899-9700 Fax : 82-31-899-9740 http://www.standardia.com