



# One Step IgG/IgM antibody to *Leptospira interrogans* Test

## 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 IgG/IgM Test is a solid phase immuno-chromatographic assay for the qualitative and differential detection of IgG and/or IgM

antibody to *Leptospira interrogans* in human serum or plasma. 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 tests like MAT reference test, ELISA, PHA must be used in order to obtain a confirmation of *Leptospira interrogans* infection.

### [PRINCIPLE]

The IgG/IgM Test has 3 pre-coated lines, "G" (*Leptospira interrogans* IgG Test Line), "M" (*Leptospira interrogans* IgM Test Line) and "C" (Control Line) on the surface of the strip. These lines in the result window are not visible before applying any samples. The "Control Line" is used for procedural control. A Control line should always appear if the test procedure is performed properly and the test reagents of the control line are working. A purple "G" or "M" line will be visible in the result window if there is enough IgG and/or IgM antibody to *Leptospira interrogans* in the sample. If IgG and/or IgM antibodies to *Leptospira interrogans* are not present in the sample, then no colour appears in the "G" or "M" line.

## 2. Materials provided

- 1) Test devices individually foil pouched with a desiccant
- 2) Assay diluent
- 3) 5ul capillary pipette

### 3. Precaution / kit storage and stability

- 1) The IgG/IgM Test should be stored at room temperature (1-30C)
- 2) The test device is sensitive to humidity 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 date.
- 5) DO NOT FREEZE.
- 6) Do not store the test kit in direct sunlight.

### 4. Specimen collection, storage and precaution

#### 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 obtain 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 obtain the serum specimen of supernatant.

3) If plasma or serum specimens are not tested immediately, they should be refrigerated at 2-8C. For a storage period longer than 2 weeks, freezing is recommended. They should be brought to room temperature (1-30C) 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 specimens to come to room temperature prior to testing.
- 2) Remove the test device from foil pouch, place it on a flat, dry surface.
- 3) [Using a capillary pipette] With a 5ul capillary pipette, add 5ul of serum or plasma specimen drawn to the black line into the square sample well marked "S".  
OR,  
[Using a micropipette] Add 5ul of serum or plasma specimen into the square sample well marked "S".


## Test Procedure


- 1** Using micropipette, add 5ul of serum or plasma into the sample well marked "S".




OR

- Using capillary pipette provided, add 5ul of serum or plasma into the sample well marked "S".


- 2** Put 4 drops of assay diluent into the round shaped well.


- 3** Interpret test results in 20 minutes.




**Do not read the results after 20 minutes. Reading too late can give false results.**

## Interpretation

**Negative**


-One pink line "C" in result window as right




**Positive**

- 1. IgG positive**


-Two pink lines "C" and "M" in result window.  
-It is positive even if "G" line is weak.


- 2. IgM positive**

-Two pink lines "C" and "M" in result window.  
-It is positive even if "M" line is weak.



- 3. IgG and IgM positive**

-Three pink lines "C", "M" and "G" in result window.



**Invalid**

-No control (C) line in result window.  
-It is recommended that the specimen be re-tested.



- 4) Add 4 drops of assay diluent to the assay diluent well round shaped.
- 5) Interpret test results in 20 minutes.

**Caution : Do not read test results after 20 minutes. Reading too late can give false results.**

## 7. Interpretation of the test

### 1) Negative

The control line is only visible on the test device. No IgG and IgM antibodies were detected.

### 2) IgM Positive

The control line (C) and IgM line (M) are visible on the test device. This is positive for IgM antibodies to *Leptospira interrogans*.

### 3) IgG Positive

The control line (C) and IgG line (G) are visible on the test device. This is positive for IgG antibodies to *Leptospira interrogans*.

### 4) IgG and IgM Positive

The control line (C), IgM (M) and IgG line (G) are visible on the test device. This is positive for both IgM and IgG antibodies to *Leptospira interrogans*.

### 5) Invalid

The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the likeliest reasons for control line failure. Repeat the test using a new test device.

## 8. Limitations of the test

- 1) This test detects the presence of IgG and 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 result does not preclude the possibility of an infection of *Leptospira interrogans*.

## 9. Bibliography of suggested reading

- 1) Henk L et al. Lateral-Flow Assay for Rapid Serodiagnosis of Human Leptospirosis. Clinic Diagnosis Lab Immunol 2001 vol 8 p 166-169
- 2) Bajani MD et al. Evaluation of four commercially available rapid serologic tests for diagnosis of leptospirosis. J Clin Microbiol. 2003 Feb;41(2):803-9.
- 3) Ryu E. Rapid microscopic agglutination test for *Leptospira* without non-specific reaction. Bull Off Int Epizoot. 1970 Jan-Feb;73(1):49-58.
- 4) Solorzano RF. A comparison of the rapid macroscopic slide agglutination test with the microscopic slide agglutination test for leptospirosis. Proc Annu Meet, U S Anim Health Assoc. 1964;68:440-4

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