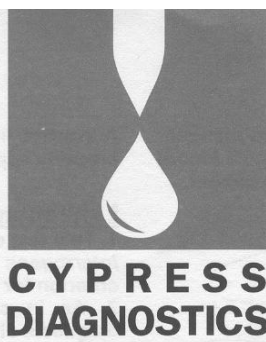


Code: 355 **Leptospira Quick Test**
25 test devices
1 vial of Diluent



Leptospira IgM Rapid Test

For the qualitative detection of IgM antibodies to *Leptospira interrogans* in human serum, plasma or whole blood

Intended use:

The Cypress Diagnostics Leptospira IgM Test is a solid phase immunochromatographic assay for the rapid, qualitative detection of IgM antibodies 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 tests like MAT reference test, ELISA, and PHA must be used in order to obtain a confirmation of *Leptospira interrogans* infection.

Summary and explanation:

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 water rafting in contaminated lakes and rivers. The incidence is also increasing among urban children.

Principle of the test:

The Cypress Diagnostics Leptospira IgM Test contains a membrane strip, which is pre-coated with *Leptospira* lysate (antigens) in the test region (T). Mouse monoclonal anti-human IgM - gold colloid, patient sample and diluent move along the membrane chromatographically to the test region (T). In the test region (T), they form a visible line as the antigen-IgM-antibody colloid gold complex is formed. Hence, the formation of a visible line in the test region (T) indicates a positive result for the detection of IgM antibodies to *Leptospira interrogans*. When antibodies to *Leptospira interrogans* are absent in the sample, no visible colored will appear in the test region.

The Control Line (C) 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.

Storage and stability:

The Cypress Diagnostics Leptospira IgM Test should be stored at room temperature between 8-30°C in the original sealed pouch. Diluent can be stored between 1-30°C. The test device is sensitive to humidity as well as to heat. Do not store in refrigerator or freeze test kits. Do not store the kit in direct sunlight. The kit is stable until the date printed on the box label and/or pouch. Do not use expired test kits.

Warnings and precautions:

1. The Cypress Diagnostics Leptospira IgM test is for *in vitro* diagnostic use only. DO NOT RE-USE test device.
2. Do not eat or smoke while handling samples.
3. Wear protective gloves while handling samples. Thoroughly wash hands afterwards.
4. Clean up spills using an appropriate disinfectant.
5. Decontaminate and dispose all samples, 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. The instruction must be followed exactly to get accurate results.

Sample collection:

The Cypress Diagnostics Leptospira IgM test is performed on whole blood, serum or plasma.

Whole blood: Collect whole blood into the collection tube (containing anticoagulants such as heparin, EDTA or sodium citrate) by venipuncture. If blood samples are not immediately tested, they should be refrigerated at 2-8°C. When stored at 2-8°C, the blood samples should be used within 3 days. For storage periods longer than 3 days, freezing is recommended. The frozen samples should be brought to room temperature (15-30°C) prior to use. When using blood samples stored for more than 3 days, nonspecific reactions may occur.

Serum: Collect whole blood into the collection tube (NOT containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture. Leave the sample for 30 minutes to provoke blood coagulation and then centrifuge the coagulated blood in order to get the serum sample.

Plasma: Collect whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture and then centrifuge to get the plasma sample.

If plasma or serum samples are not immediately tested, they should be refrigerated at 2-8°C. For storage periods longer than 2 weeks, freezing is recommended. The frozen samples should be brought to room temperature (15-30°C) prior to use. Plasma or serum samples containing a precipitate may yield inconsistent test results. For this reason, they must be clarified prior to use.

Anticoagulants such as heparin, EDTA, and citrate do not affect the test result. However, the use of hemolytic, lipaemic, icteric or rheumatoid factors containing samples should be avoided because it can lead to impaired results.

Use new capillary pipettes or pipette tips for each sample in order to avoid cross-contamination of samples, which could cause erroneous results.

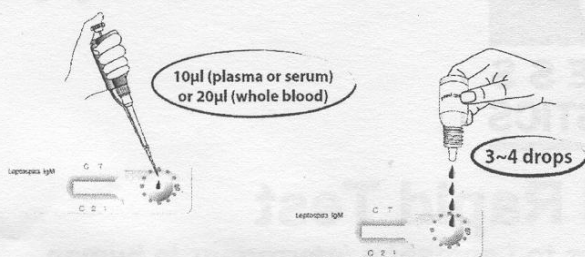
Test Procedure:

1. Bring all test devices, reagents and samples to room temperature (15 ~ 30°C) prior to testing.
2. Use a new test device for every sample. The device is not reusable.
3. Just prior to use, remove the test device from the foil pouch, and place it on a flat, dry surface.

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- Label the test unit with patient name or identification number.
- Slowly add 10 µl of serum or plasma (or 20 µl of whole blood) to the sample well and then add 3~4 drops of assay diluent.



- After adding sample and diluent, colored band moves across the result window in the center of the test device. This indicates that the test is running.
- Interpret the test results at 15~20 minutes.
- Do not interpret the test results after 20 minutes, as this can give false results.

Interpretation of results:

A colored band will appear at the left section of the Results Window to show that the test is properly working. This band is the Control Band ("C").

The right section of the Results Window indicates the test results. If a colored band appears at the right section of the Results Window, this band is the Test Band ("T").

Positive

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



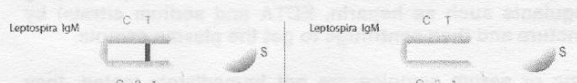
Negative:

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



Invalid:

If the control band is not visible within the result window after performing the test, the result is considered invalid. The instructions may not have been correctly followed or the test may have deteriorated. It is recommended to re-test the sample.



Quality control:

A control line ("C") should always appear in the control area if the test reagents of the control line are properly working, the assay diluent has been properly applied, and the instructions have been properly followed.

A control line does not guarantee that the sample has been properly applied, or that the sample was correctly stored.

Limitations of the procedure:

- This test detects the presence of IgM antibodies to *Leptospira interrogans* in the sample and should not be used as the sole criterion for the diagnosis of leptospirosis.
- As in case of all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test but should rather be made by a physician after all the clinical findings have been evaluated.
- If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result does not preclude the possibility of an infection of *Leptospira interrogans*.

Performance Characteristics:

Comparison study

The Cypress Diagnostics Leptospira IgM test was analyzed with positive and negative clinical samples that were confirmed by MAT. The test was also compared to a leading commercial PHA kit.

Table 1: Serological Sensitivity and Specificity of the Cypress Diagnostics Leptospira IgM test

Sample	Cypress Quick test			Commercial PHA test		
	+	-	Total	+	-	Total
+	53	2	55	52	3	55
-	7	143	150	8	142	150
Total	60	145	205	60	145	205

In these studies, the Cypress Diagnostics 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.

Precision

Within run precision was determined by using 10 replicates of four different samples containing different concentrations of antibody. All values (negative and positive) correlated for 100%.

Between run precision was determined by using the four different samples containing different concentrations of antibody in 3 different replicates with 3 different lots of test devices. Again, all values (negative and positive) correlated for 100%.

References:

- 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.
- 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.
- 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.

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