ACCUCARE™

LEPTOSPIRA IgG/IgM Rapid Test

(Serum/Plasma)

A rapid and sensitive test for the qualitative detection of IgG,IgM antibodies to the Leptospira organisms in human serum/plasma.
Only for *In vitro diagnostic* use

ORDER INFORMATION

REF	Cont.
LEPC 1	1 Test
LEPC 10	10 Test
LEPC 25	25 Test

CLINICAL SIGNIFICANCE

The clinical manifestations of leptospirosis range from a mild catarrh like illness to icteric disease with severe liver and kidney involvement. Natural reservoirs for leptospirosis include rodents as well as a large variety of domesticated mammals. 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. (veterinarians, abattoir workers, or dairy workers) or by exposure to environment contaminated by animal carriers (e.g. agricultural workers). 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.

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.

KIT COMPONENTS

Test Device, Assay Buffer, Sample Dropper and product insert.

STORAGE & STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed pouch until use. Do not freeze.
2. Do not use beyond the expiration date.
3. Do not use the test kit, if the pouch is damaged or seal is broken.

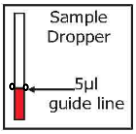
SPECIMEN COLLECTION & PREPARATION

Fresh Serum or Plasma: If testing is not performed within 3 days of collection of specimen, the specimen should be refrigerated immediately at 2-8°C.

PRECAUTIONS

1. Wear protective gloves while handling specimens wash thoroughly afterwards.
2. The device is sensitive to humidity as well as heat. Therefore take out the device from seal pouch before test.
3. Do not mix reagents from different lot.
4. Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
5. Follow the testing procedure exactly as mention in the insert.

DIRECTIONS FOR USE



1. Place the test device on a clean and flat surface. Hold the dropper vertically and suck 5 µl of serum, plasma up to notch level and then press dropper to dispense sample in to the sample well (S) of the test device,
1. Add 2 drops (70-80 µL) of buffer to the buffer well of the test device immediately after the specimen is added, and then start the timer.
2. Wait for the red line (s) to appear. The test result should be read at 15 minutes. It is important that the background is clear before the result is read.

INTERPRETATION OF THE RESULTS

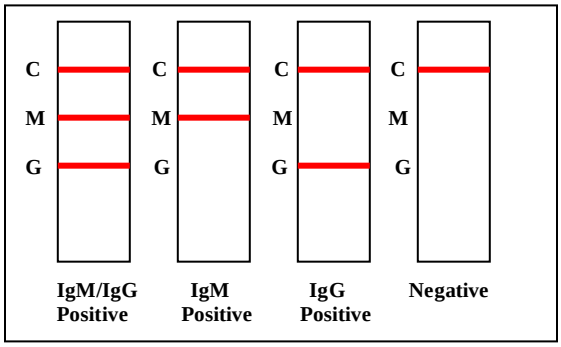
IgM POSITIVE: Two distinct red lines appear. The control line (c) and IgM (M) line are visible on the test cassette. This is positive for IgM antibodies to Leptospira interrogans.

IgG POSITIVE: 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.

IgG/IgM POSITIVE: 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.

NEGATIVE: One distinct red line appears. The control line (c) is the only line visible on the test cassette. No IgM/IgG antibodies were detected. The result does not exclude Leptospira infection.

INVALID: Control line fails to appear. The test results are INVALID, if no control line (C) is visible, regardless of the presence or absence of line in the IgM(M)/IgG(G) region of the cassette. Repeat the test using a new cassette.



PERFORMANCE CHARACTERISTICS

Clinical Performance for IgM Test

A total of 210 samples from susceptible subjects were tested by the Leptospira IgG/IgM Combo Rapid Test and by a commercial Leptospira IgM EIA kit. Comparison for all subjects is shown in the following table.

	Leptospira IgG/IgM Rapid Test		
IgM EIA	Positive	Negative	Total
Positive	9	1	10
Negative	2	198	200
Total	11	199	210

Relative Sensitivity: 90.0%, Relative Specificity: 99.0%, Overall Agreement: 98.6%

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Clinical Performance For IgG Test

A total of 206 samples from susceptible subjects were tested by the Leptospira IgG/IgM Rapid Test and by a commercial Leptospira IgG EIA kit. Comparison for all subjects is shown in the following table.

	Leptospira IgG/IgM Rapid Test		
IgG EIA	Positive	Negative	Total
Positive	6	0	6
Negative	2	198	200
Total	8	198	206

Relative Sensitivity: 100%, Relative Specificity: 99.0%, Overall Agreement: 99.0%

LIMITATIONS

1. The test procedure, precautions and interpretation of results for this test must be followed when testing.
2. The intensity of the red color in the test line regions (IgM/IgG) will vary depending on the concentration of IgG/IgM present in the specimen. However, neither the quantitative value nor the rate of increase in IgG/IgM can be determined by this qualitative test.
3. A negative result can occur if the quantity of the anti- Leptospira antibodies present in the specimen is below the detection limits of the assay or the antibodies that are detected are not present during the stage of disease. Other clinically available tests are required. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

BIBLIOGRAPHY

1. Kelly PW. Leptospirosis. In, Infectious disease in medicine and surgery. Gorbach S, Barlett J, Balcklow N, (eds): Philadelphia, Saunders, 1991, pp. 1295-1302.
2. Ribeiro MA, Assis CSN, Romero EC. Serodiagnosis of human leptospirosis employing immunodominant antigen. Serodiagn. Immunother. Infect. Disease 1994; 6: 140-144.

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