LEPTOSPIRA IgG/IgM

METHOD – LATERAL FLOW IMMUNOASSAY
PRODUCT CODE – RC14

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

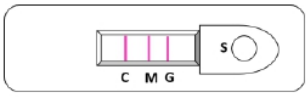
INTENDED USE: Test for detection of IgG/IgM antibodies to Leptospira organisms in human serum and plasma samples.

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 Instructions for use.

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.

STORAGE & STABILITY

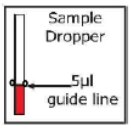
The kit can be stored at room temperature or refrigerated (2-30 °C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND 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.

TEST PROCEDURE

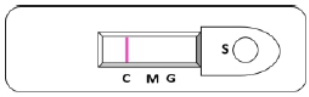
Allow test cassette, specimen, and/or controls to equilibrate to room temperature (15-30 °C) prior to testing.



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.
2. 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.
3. 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

NEGATIVE RESULT: One band appears in the control region (C). No apparent bands appears in the test regions (M or G).



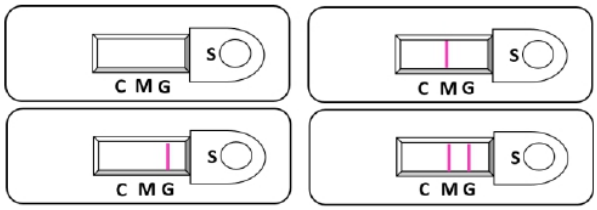
POSITIVE RESULT:

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.

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 and 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.

INVALID TEST: No visible band at the control region. Repeat with a new test device.



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		**98.60%**	

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%**	

QUALITY CONTROL

Although the testing device contains an internal quality control (coloured band in the control region), good laboratory practice recommends to run a known positive and negative control sample to ensure proper performance. All controls should be handled in the same manner as patient

LIMITATIONS

1. The test procedure, precautions and interpretation of results for this test must be followed when testing.
2. The intensity of the red colour 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.

SYMBOLS: Read Instruction for use | IVD In Vitro Diagnostic Use Only | Manufactured by | Expiry Date | Storage Temperature

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ISO 9001 : 2015
ISO 13485 : 2003
GMP
CE