

One step rapid Card Test for detection of IgG and IgM antibodies to the Leptospirosis in human Serum/Plasma

Store at 2-30°C. DO NOT FREEZE.
For In-Vitro Diagnostic Use only

ORDER INFORMATION

Pack Size	REF
01 Test	LEPC 01
10 Tests	LEPC 10
25 Tests	LEPC 25

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 ACCUCARE® ONE STEP LEPTOSPIRA IgG/IgM RAPID 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.

CONTENTS

- Test Device
- Assay Buffer
- Instruction for Use (IFU)
- Disposable (Dropper) 5 µl sampling device
- Desiccant

STORAGE & STABILITY

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

PRECAUTIONS

1. For professional *In-vitro* diagnostic use only. Do not use after expiration date.

2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all the specimens as potentially infectious. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens and tested device.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5. Read the Instruction for use carefully before performing the test.

LIMITATIONS

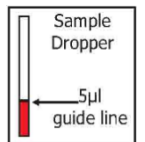
1. ACCUCARE® ONE STEP LEPTOSPIRA IgG/IgM RAPID TEST detects the presence of LEPTOSPIRA IgG & IgM antibodies and should not be used as the sole criteria for the diagnosis of Leptospirosis infection.
2. As with all diagnostic tests, all results must be correlated with other clinical findings. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result at any time does not preclude the possibility of an early infection of Leptospirosis.
3. This is only a screening test. 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.

SPECIMEN COLLECTION & PREPARATION

1. The ACCUCARE® ONE STEP LEPTOSPIRA IgG/IgM RAPID TEST can be performed using either serum or plasma.
2. Separate the serum or plasma from whole blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
5. If specimens are to be shipped, it should be packed in compliance with federal regulations for transportation of etiologic agents.

PROCEDURE

1. Allow test device, Assay Buffer and specimen equilibrates to room temperature (15-30°C) prior to testing.
2. Remove the test device from the aluminum foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
3. Place the test device on a clean and flat surface. Carefully dispense 1 drop (5 µl) of Serum/Plasma in the sample well "S" using the dropper provided.
 - Take a sample dropper, and while gently squeezing the tube, immerse the open end in the blood drop and then gently release the pressure to draw blood into the sample dropper upto the mark line.

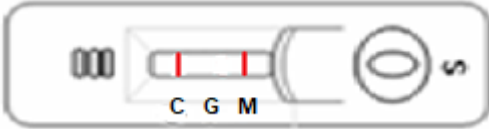


4. After that add 2 drop (appx. 60 µl) of Assay Buffer in the sample well "S".
5. Allow reaction to occur and read the results at 15 minutes. Do not interpret the results after 20 minutes.

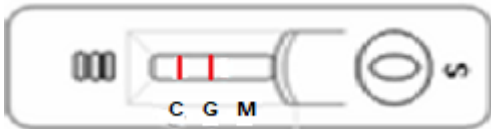
INTERPRETATION OF RESULTS

1. POSITIVE

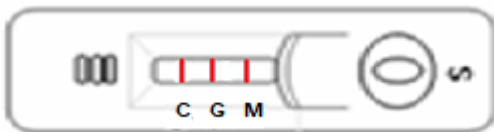
- If two color lines appear, one at control region 'C' and other at test region 'M', the specimen is positive for Leptospira IgM Antibody.



- If two color lines appear, one at control region 'C' and other at test region 'G', the specimen is positive for Leptospira IgG Antibody.

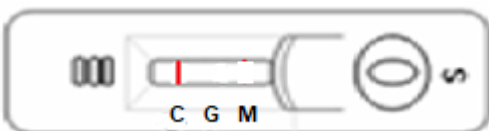


- If three color line appear, one at control line 'C', one at test region 'G' and one at test line 'M', the specimen is positive for both Leptospira IgG & IgM Antibody.



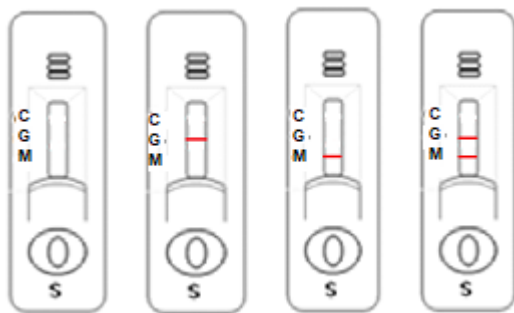
2. NEGATIVE

If only one color band appear at control line 'C' as the specimen is Negative for Leptospira IgG & IgM Antibody.



3. INVALID

If no color band appear, at control line 'C' within the stipulated time then result is invalid. Repeat the test using a fresh Test Device.



PERFORMANCE CHARACTERISTICS

The ACCUCARE® ONE STEP LEPTOSPIRA IgG/IgM RAPID TEST has been evaluated with positive and negative samples confirmed by ELISA examination.










Specimen	Positive	Negative	Sensitivity
IgG Positive	24	1	96.0%
IgM Positive	19	1	95.0 %
IgG + IgM Positive	43	2	95.5 %

Specimen	Positive	Negative	Specificity
Negative	5	95	95.0 %

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.

GLOSSARY OF SYMBOL

	Consult Instruction for Use	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer		Do not reuse
IVD	For <i>in vitro</i> Diagnostic use only		Keep Dry
	Tests per Kit		Do Not Use if Damaged