Leptospira IgM Rapid Test
(Serum / Plasma / Whole Blood)

INTENDED USE
First View Leptospira IgM Rapid test for detection of IgM antibodies to Leptospira is an immunochromatographic assay for the qualitative Detection of Leptospira specific IgM antibodies in human serum/plasma or whole blood.

SUMMARY AND EXPLANATION OF THE TEST
Leptospirosis is a disease caused by the bacteria Leptospira. Humans can get leptospirosis through direct contact with urine from infected animals or through water, soil or food contaminated with their urine. It's most common in warm climates. High fever, headache, bleeding, muscle pain, chills, red eyes and vomiting are some symptoms. Without treatment, leptospirosis can lead to kidney and liver damage and even death. Antibiotics treatment can cure the infection. Hence, the timely diagnosis plays an important role to control it.

TEST PRINCIPLE
After addition of the serum or plasma and the assay buffer to the sample well of the device containing a test strip, the sample moves on to the conjugate pad containing colloidal gold particles conjugated with human IgM specific antibodies and streptavidin. If the sample contains detectable levels of the Leptospira specific IgM antibodies, it reacts with the gold conjugated human IgM specific antibodies to form a complex. This complex moves further reacts with recombinant Leptospira antigen test line coated on the nitrocellulose membrane area to form colored band. The unbound complex and the Streptavidin conjugated colloidal gold particles move further to the Biotin coated control area to form a colored band (Control line). The appearance of test line/s and control line in respective area indicates the positive result. Appearance of only control line indicates a negative result. The control line acts as a procedural control. Control line should always appear if the test is performed as per the procedure and reagents are working properly.

REAGENTS AND MATEREIALS PROVIDED
Leptospira IgM test cards contain the following:
- Test Device with activated silica gel
- Plastic Dropper.
- Assay Buffer Bottle
- Package Insert (Instruction for use)

MATERIALS MAY BE REQUIRED BUT NOT PROVIDED
- Positive Control
- Negative Control

MATERIALS REQUIRED BUT NOT PROVIDE
- Timer
- Digital Clock
- Specimen collection container Tube

WARNINGS AND PRECAUTIONS:
For in Vitro Diagnostic Use
- This package insert must be read completely before performing the test.
- The test device should remain in the sealed pouch until use
- Do not use expired devices.
- Do not use the kit if the cassette package is damaged or the seal is broken.
- Bring all reagent to room tempreature (15-30°C) before use.
- Do not use hemolyzed blood specimens for testing.
- Wear personal protective equipment,such as gloves and lab coats when handling kit reagents.wash hands thoroughly after performing the test.
- Do not smoke,drink or eat in areas where specimens or kit reagents are being handled.
- Dispose of all specimens and material used to performe the test as bio-hazardous waste.

REAGENT PREPARATION AND STORAGE
INSTRUCTIONS: All reagents are ready to use as supplied. Store unused test device unopened at 2-30 °C, ensure that the test device brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperature 30°C.

SPECIMEN COLLECTION, STORAGE AND HANDLING
Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

1. Plasma
- **Step 1:** Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively, in Vacutainer) by venipuncture.
- **Step 2:** Separate the plasma by centrifugation.
- **Step 3:** Carefully withdraw the plasma into a new pre-labeled tube.

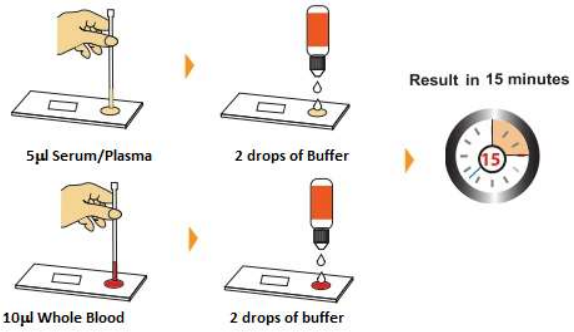
2. Serum
- **Step 1:** Collect blood specimen into a red top collection tube (containing no anti coagulants in Vacutainer by venipuncture.
- **Step 2:** Allow the blood to clot.
- **Step 3:** Separate the serum by centrifugation.
- **Step 4:** Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store Specimens at 2-8°C if not tested immediately, for up to 5 days. The specimens should be frozen at -20°C for longer storage.

3. Whole Blood
- Drops of whole blood can be obtained by either finger tip puncture or venipuncture. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer). Do not use hemolyzed blood for testing.
- Whole blood specimens should be stored in refrigeration (2-8°C),if not tested immediately. The specimens must be tested within 24 hours of collection.

DIRECTIONS FOR USE
Allow test cassette, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
1. Bring the pouch to room temperature before opening it.
2. Remove the test cassette from the sealed pouch and place it on flat dry surface.
3. **For Serum or Plasma Specimen**: Hold the dropper vertically and transfer **1 drop** of serum or plasma (**approximately 5µl**) to the specimen area, then add **2 drop** of buffer **(approximately 80µl),** and start the timer, see illustration below.

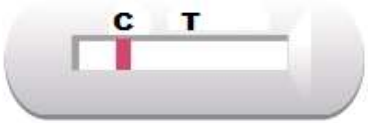
   .For Whole Blood Specimen: Hold the dropper vertically and transfer **2 drop** of whole blood (**approximately 10µl**) to the specimen area, then add **2 drops** of buffer (**approximately 80µl**), and start the timer. See illustration below.



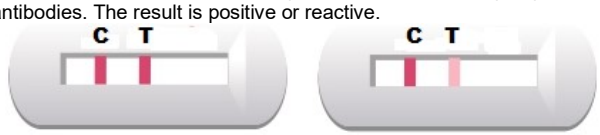
4. Wait for the colored line(s) to appear. The test result should be read at 15 minutes.

   Note. ***Do not interpret the result after 20 minutes***

INTERPRETATION OF ASSAY RESULT
1. **NEGATIVE RESULT:** If only the Cline is developed, the test indicates that the level of Leptospira antibodies in the specimen is undetectable. The result is negative or non-reactive.



2. **POSITIVE RESULT:** If both the C and the T lines are developed, the test indicates that the specimen contains Leptospira antibodies. The result is positive or reactive.



Samples with reactive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.

3. **INVALID:** If no C line is developed, the assay is invalid regardless of color development on the T line as indicated below. Repeat the assay with a new device.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

PERFORMANCE CHARACTERISTICS.

1. Clinical Performance.

A total of 151 samples from susceptible subject were tested with the First View Leptospira IgM Rapid Test and with a commercial Leptospira IgM ELISA KIT. Comparison for all subjects is shown in the following table**.**

Sample	First View Leptospira IgM		Reference	
	Positive	Negative	Positive	Negative
Positive	51	0	51	0
Negative	0	100	0	100
Total	51	100	51	100

Relative Sensitivity : 100%
Relative Specificity : 100%,
Accuracy : 100%.

2. Cross-reactivity

The Leptospira IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested HIV, HCV, H. Pylori, HBsAg and syphilis Ab positive specimens. The results showed no cross-reactivity.

EXPECTED VALUES

The First View Leptospira IgM Rapid Test Card (Serum/Plasma/Whole Blood) has been compared with a leading commercial Leptospira IgM ELISA test, demonstrating an overall accuracy greater than or equal to 100%

LIMITATIONS

1. As with all diagnostic tests, the test result must always be correlated with clinical findings.
2. The results of test are to be interpreted within the epidemiological, clinical and therapeutic context.
3. Any modification to the above procedure and / or use of other reagents will invalidate the test procedure.

LIMITED EXPRESS WARRANTY DISCLAIMER

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