

# EURO Leptospira IgG/IgM Rapid Test

10 Tests

Only for in vitro use in clinical laboratory (IVD)

## Intended Use

EURO Leptospira IgG/IgM Rapid Test Kit is a qualitative immunochromatographic assay for the detection of IgG and IgM antibodies produced against *Leptospira interrogans* in whole blood, or serum.

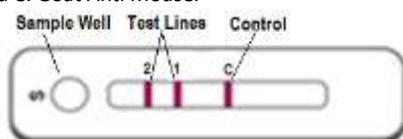
## Clinical Significance

Leptospirosis is a bacterial disease that affects both humans and animals. Humans become infected through direct contact with the urine of infected animals or with a urine-contaminated environment. The bacteria enter the body through cuts or abrasions on the skin, or through the mucous membranes of the mouth, nose and eyes. Without treatment, Leptospirosis can lead to kidney damage, meningitis (inflammation of the membrane around the brain and spinal cord), liver failure, respiratory distress, and even death.

Euro Leptospira IgG/IgM antibody Rapid Test is for the qualitative determination of IgG and IgM antibodies developed during Leptospirosis infection.

## Principle

EURO Leptospira IgG/IgM Rapid test works on chromatographic immunoassay. Basic components of each test strip includes: a) Conjugate pad which contains colloidal gold conjugate; b) a nitrocellulose membrane strip containing two lines T2: Anti human IgM, T1: Anti human IgG and C: Goat Anti Mouse.



Test sample that is added to the sample well (S), with adequate amount of buffer migrates from the sample pad along the conjugate pad where *Leptospira* specific IgG/IgM present in the sample will bind to Colloidal Gold conjugate to form a complex. The sample then continues to migrate across the membrane until it reaches the capture zones where the complex accordingly will bind to the immobilized Anti Human IgG/IgM (on test lines) producing a visible lines on the membrane. If the respective antibody is not present in the sample, no reaction occurs in the capture zones and no test line is formed. The sample then migrates further along the strip until it reaches the control zone, where it produces another visible line on the membrane. This control line indicates that the sample has migrated across the membrane as intended.

## Kit Components

- Each test pouch contains :
  - One test card and dropper
  - Desiccant
- Assay Diluent- In dropper bottle
- Instruction Leaflet

## Storage and Stability

Store the test kit between 4-30°C till the expiration date indicated on the pouch / carton. DO NOT FREEZE. Ensure that the test device is brought to room temperature before opening.

## Precuation and Warning

- Use within 10 minutes after opening pouch.
- Do not touch result window.
- Use only the buffer supplied along with the kit.
- Do not mix components from different kits.
- Use only for in-vitro diagnostic purpose.
- Treat all specimens, used tests and other contaminated materials as infectious, and dispose accordingly.
- Do not use with hemolytic, lipemic or bacterially contaminated specimen.
- Do not use with specimen containing precipitates

## Materials Required but not provided

Specimen Collection tubes, Centrifuge, Timer

## Specimen Collection and Preparation

Specimen: Blood, Serum

### Blood:

Collect the whole blood using a syringe or vacutainer into a container containing anticoagulants such as heparin, EDTA or sodium citrate by venipuncture.

### Serum:

Collect the whole blood using a syringe or vacutainer (NOT containing anticoagulants such as heparin, EDTA or sodium citrate) by venipuncture. Leave the syringe or vacutainer, preferably at an angle, to settle for 30 minutes. Once blood coagulates, centrifuge the blood to get serum specimen as supernatant.

- If the specimen is not used for testing immediately, they should be refrigerated at 2~8°C.
- For storage period longer than 5 days, freezing is recommended. Store at -20°C
- The specimen should be brought to room temperature prior to use.

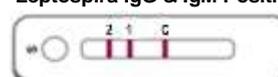
**Treat the specimen as infectious and handle with standard biosafety measures**

## Procedure:

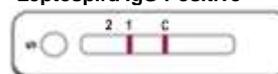
- Take out the test card from the foil pouch and place it on a horizontal surface.
- Add 10 µl of Whole Blood/Serum to the Sample well "S"
- When the sample is fully absorbed, add 2 drops of the diluent provided with the assay to the sample hole.
- Wait for 15 minutes and interpret results. All results where control band does not appear are Considered invalid.

## Results

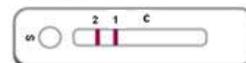
### Leptospira IgG & IgM Positive



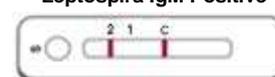
### Leptospira IgG Positive



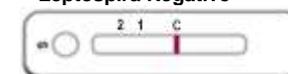
### Invalid



### Leptospira IgM Positive



### Leptospira Negative



Manufactured by : ubio Biotechnology Systems Pvt Ltd, cochin, KL

Marketed By: Euro Diagnostic Systems Pvt. Ltd.,  
36/37 "MillenniumHouse", M.K. Srinivasan Nagar Main Road, Perungudi,  
Chennai – 600 096; Ph: 044-2496 0541 Email: [euroidspl@gmail.com](mailto:euroidspl@gmail.com),  
[www.eurodiagnostics.in](http://www.eurodiagnostics.in), Customer Care no: 09382717071