

## Instructions for Use

Version: 1.0.1  
Revision date: 10-Apr-24

# Leptospira IgG / IgM Rapid Test Kit

**Catalog No.:** abx092260

**Size:** 400 tests / 1920 tests / 10000 tests

**Storage:** Store all reagents at 4-30 °C. Keep dry. Do not freeze.

**Application:** For qualitative detection in human serum, plasma, or whole blood.

### Introduction and assay principle

Abbexa's Leptospira IgG / IgM Rapid Test Kit is a lateral flow immunoassay which can detect antibodies against Leptospira. The sample pad inside the cassette contains gold nanoparticles coated with Leptospira antigen, and mouse IgG. Antibodies against human IgM and IgG are coated in their respective regions on a nitrocellulose membrane, creating the test lines and goat anti-mouse IgG antibodies are coated on the control line. The control region on the upper end of the cassette confirms if the test has been successful.

#### Kit Components

- Test cassettes
- Sample diluent

#### Material Required But Not Provided

- Timer
- High-precision pipette and sterile pipette tips
- Paper towel (or similar)
- Soap and clean water

### Sample preparation

- **Serum:** Samples should be collected into a serum separator tube. Coagulate the serum by leaving the tube undisturbed at room temperature for 30 min. Centrifuge at approximately 1000 × g for 15 mins between 2-8°C. If a precipitate appears, centrifuge again. Take the supernatant and assay immediately, or aliquot the supernatant and store between 2-8°C for up to 5 days, or at -20°C for long-term storage.
- **Plasma:** Collect plasma using an anticoagulant tube. Centrifuge for 15 mins at 1000 × g between 2-8°C, within 30 mins of collection. If precipitate appears, centrifuge again. Take the supernatant and assay immediately, or aliquot the supernatant and store between 2-8°C for up to 5 days, or at -20°C for long-term storage.
- **Whole blood (venipuncture):** Collect whole blood using an anticoagulant tube, then assay immediately or store between 2-8°C for up to 24 hours. Do not freeze whole blood samples.
- **Whole blood (fingerstick):** Wash hands thoroughly with soap and water. Ensure fingertips are clean and dry. Using a lancet, press against the fingertip to puncture. Use a clean paper towel or similar material to wipe off the first drop of blood. Gently massage the finger from knuckle to fingertip to allow a second drop of blood to form. Immediately collect 20 µl (approximately one drop) of blood and assay immediately.
- **Notes:** Fresh samples are recommended. Avoid repeated freeze/thaw cycles, bacterial pollution, visible particles; and avoid cloudy, hemolytic, or viscous samples. Bring samples to room temperature before carrying out the assay.

### Assay procedure

1. Bring all kit components and samples to room temperature.
2. Take a test cassette and lay it flat on a clean table.
  - Whole blood samples:
    - a) Add 1 drop (approximately 40 µl - 50 µl) of whole blood sample to the sample well on the test cassette.
    - b) Add 2 drops (approximately 70 µl -100 µl) of sample diluent to the sample well on the test cassette. Start the timer.
  - Serum and plasma samples:
    - a) Add 1 drop (approximately 30 µl – 45 µl) of serum or plasma sample to the sample well on the test cassette.

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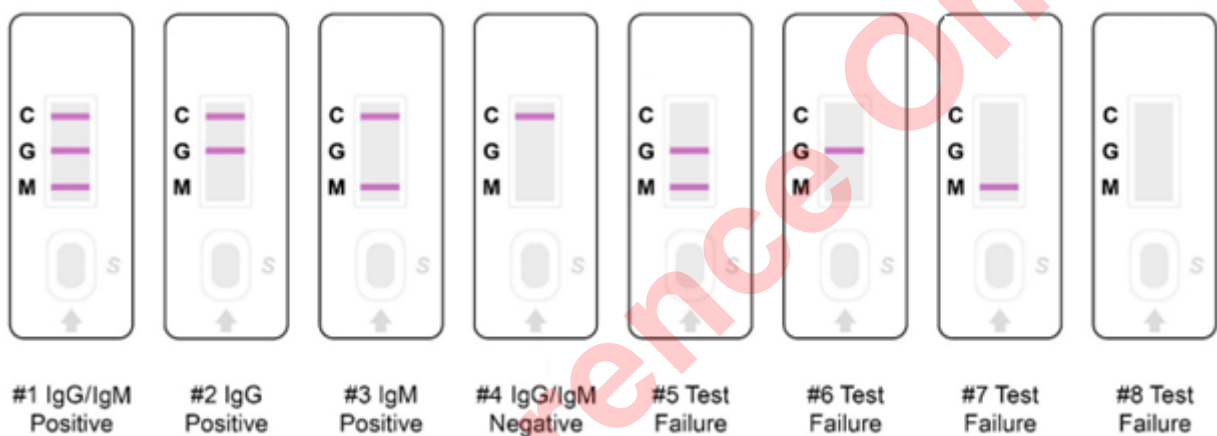
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- b) Add 2 drops (approximately 70  $\mu$ l – 100  $\mu$ l) of sample diluent to the sample well on the test cassette. Start the timer.
3. Leave at room temperature for 15 min, then analyze the result.

### Results analysis

- **IgG and IgM Positive result:** A colored line is observed in the control (C) section and both test sections (IgG and IgM).
- **IgG Positive result, IgM Negative result:** A colored line is observed in the control (C) section and the first test section (IgG) but not the second test section (IgM).
- **IgM Positive result, IgG Negative result:** A colored line is observed in the control (C) section and the second test section (IgM) but not the first test section (IgG).
- **IgG and IgM Negative result:** A colored line is observed in the control (C) section but not in the test sections (IgG and IgM).
- **Invalid result:** No colored line is observed in the control (C) section.



### Notes

1. The test cassettes and samples should be brought to room temperature before use.
2. After opening the aluminum foil, use the test cassette as soon as possible.
3. Do not mix or re-use disposable pipettes or pipette tips to avoid cross-contamination.
4. Avoid touching the cassette membrane through the sample well or test result window.
5. False positive results can be caused by several factors, such as: cross-reaction of similar antibody components in blood; cross-contamination of samples during transportation and treatment; contamination of test components during the assay.
6. False negative results can be caused by several factors, such as: components in the sample blocking the antigen epitope, preventing the antigen from binding to the antibody; sample degradation; analyte concentration is lower than the detection limit of the kit.
7. This kit is for qualitative detection of *Leptospira* IgG / IgM antibodies in human serum, plasma, and whole blood samples. For other sample types, a preliminary experiment is recommended to determine compatibility with this kit.
8. This kit is for research use only and the results are for reference only. It is recommended to use this kit in conjunction with another detection method.
9. All waste should be disposed appropriately. Please note that you may need to follow special waste disposal procedures for infectious samples. Please check local disposal regulations.