ASTAM DIAGNOSTICS

PRODUCT INSERT

REF LATD

PRATHAM®

LEPTOSPIRA ANTIBODY TEST (IgM & IgG)

INTENDED USE

Pratham® Laptospira Antibody Test (IgM & IgG) is a rapid immunoassay based upon chromatography principle for the qualitative detection of IgM & IgG Ab to Leptospira organism present in the human Serum / Plasm / Whole blood. For professional and in-vitro diagnostic use only.

INTRODUCTION

Leptospira are actively motile, delicate spirochaetes possessing a large number of closely wound spirals and characteristic hooked ends. There are several species of Leptospira and they may be saprophytic or parasitic. They can be distinguished only under dark ground illumination in the living state or by electron microscopy. Leptospirosis is a zoonotic disease of worldwide prevalence. Humans are infected when the water contaminated by the urine of carrier animals enters the body through cuts or abrasions on the skin or through intact mucosa of the mouth, nose or conjunctiva. Clinical symptoms include fever, chills, headache, conjunctivitis, myalgia and GI related symptoms, Kidney infection is a common sequella. Diagnosis may be made by demonstration of Leptospira microscopically in blood or urine, by isolating them in culture or by inoculation of Guinea pigs or by serological tests.

TEST PRINCIPAL

Pratham® Leptospira Antibody Test (IgM & IgG) 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 result window are not visible before applying any samples. The "Control Line" is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working. A purple "G" or "M" line will be visible in the result window if there are enough IgG and / or IgM antibody to Leptospira interrogans in the sample. If IgG and / or IgM antibody to Leptospira interrogans are not present in the sample, there is no color appears in "G" or "M" line.

KIT COMPONENTS

1. Individually sealed foil pouches containing:
   a. One cassette device
   b. One desiccant
   c. Plastic dropper
2. Assay Buffer
3. Instruction for use

MATERIAL REQUIRED BUT NOT PROVIDED

Timer, Gloves Micropipette, tips & centrifuge etc.

STORAGE AND STABILITY

Pratham® Leptospira Antibody Test (IgM & IgG) device should be stored at 2-40ºC in the cool & driest place. Once the pouch is opened, test card must be used immediately. The kit should not be frozen & must be protected from exposure to humidity and direct sunlight.

SPECIMEN COLLECTION AND STORAGE

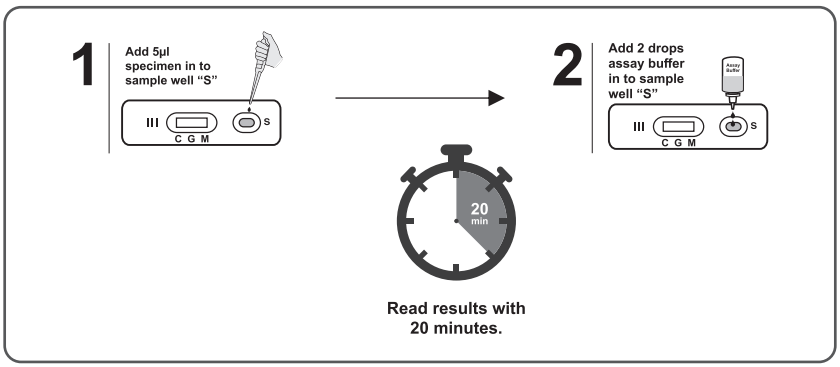
1. No prior preparation of the patient is required.
2. Collect blood specimen by venipuncture according to the standard procedure.
3. Specimen (serum / plasma / whole blood) should be free of particulate matter and microbial contamination.
4. Preferably use fresh sample. However, specimen can be stored refrigerated fro short duration. For long storage, freeze at -200C or below. Do not freeze whole blood samples. Specimen should not be frozen and thawed repeatedly.
5. Do not heat inactivate before use.
6. Turbid sample (microbial contamination) should not be used.
7. Specimens containing precipitate or particulate matter should be centrifuged prior to use.

WARNING AND PRECAUTIONS

- Use product insert to perform the assay.
- Failure to follow the insert gives inaccurate test results.
- Do not use expired kit.
- Use separate sample collection tube or micro pipette tips for each sample to avoid cross contamination.
- Do not use hemolized blood specimens for testing.
- Do not throw away used device, sample tube and tips anywhere discard it in proper way as bio hazardous waste.
- Use of disposable gloves and bio-hazardous clothing while running the test.
- The Test shall be performed by competent person only.
- Bring all reagents and specimen to room temperature before use.
- Spills should be decontaminated promptly with IPA or any other suitable disinfectant.
- Do not unwrap the packed until it attains room temperature.
- Do not re-use the test device.

TEST PROCEDURE

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible
2. Check the packaging is not damaged. If damaged, discard the test and use another test.
3. Open the pouch & check the desiccant. If color of desiccant does not show any change (Remains blue) you can use the test. If color changes then discard the test and use another test.
4. Add 5µl of serum, plasma or whole blood into the sample well with the help of provided dropper in the kit.
5. Add 2 drops of assay/running buffer into the sample well using provided buffer vial.
6. Interpret test results within 20 minutes. Don't interpret results after 20 minutes.



INTERPRETATION OF RESULTS

NEGATIVE:

If only the C line is present, the absence of any color in both test lines (M and G) indicates that no detectable anti-L. interrogans antibody is present in the specimen. The result is negative or non-reactive.

IgM POSITIVE:

In addition to the presence of the C line, if only the M line develops, the test indicates the presence of anti-L. interrogans IgM. The result is anti-L. interrogans IgM positive or reactive.

IgG POSITIVE:

In addition to the presence of the C line, if only the G line develops, the test indicates the presence of anti-L. interrogans IgG. The result is anti-L. interrogans IgG positive or reactive.

IgG & IgM POSITIVE:

In addition to the presence of the C line, both the M and the G lines develop, the test indicates the presence of the both anti-L. interrogans IgG and IgM. The result is both anti-L. interrogans IgG and IgM positive or reactive.

INVALID:

If no line develops, the assay is invalid regardless of any color in the test lines as indicated below. Repeat the assay with a new device.

INTERNAL QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. External controls are not supplied with this kit. It is recommended that positive and negative controls should be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance. Handle the negative and positive controls in the same manner as patient specimens.

DISPOSAL

Consider all test devices run with human specimen as potentially infectious and discard using standard biosafety practices.

DISCLAIMER:

Every precaution has been taken to ensure diagnostic ability and accuracy of this product. This product is used outside the control of manufacturer and distributors. Various factors including storage temperature, environment conditions, and procedural errors may affect the result. A person who is subject of the diagnosis should consult a doctor for further confirmation.

WARNING

The Manufacturer and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative in the use of this product.

REFERENCES

1. Cumberland PC, Everard COR, Levett PN. Assessment of the efficacy of the IgM enzyme-linked immunosorbent assay (ELISA) and microscopic agglutination test (MAT) in the diagnosis of acute leptospirosis. Am J Trop Med Hyg. 1999;61:731-734.
2. Adler B, Murphy AM, Locarnini SA, Faine S. Detection of specific anti-leptospiral immunoglobulins M and G in human serum by soli-phase enzyme-linked immunosorbent assay. J ClinMicrobiol. 1980;11:452-457.
3. henk L et al. Lateral Flow Assay for Rapid Serodiagnosis of Human Leptospirosis. Clinic Diagnosis Lab Immunol 2001 vol 8 p 166-169.

SYMBOLS

Read instructions for use	Name of Manufacturer	For single use only
No. of test	Expiry Date of Kit.	Date of manufacturing of IVD Kit

IVD In-vitro diagnostic use	Keep away from Sunlight	REF Reference Catalogue Number
Storage Condition		

ASTAM DIAGNOSTICS

Manufactured By:
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