ASTAM DIAGNOSTICS

PRODUCT INSERT

REF KATD

PRATHAM® Kala Azar Antibody Test Device

A lateral flow chromatographic immunoassay for the qualitative detection of IgG antibody of Leishmania (Kala Azar) in human serum / plasma / whole blood.

INTENDED USE

PRATHAM® Kala Azar Antibody Test Device is a rapid, qualitative, two site sandwich immunoassay for the determination of antibodies to Visceral Leishmaniasis (VL), members of L. donovani, in human serum / plasma / whole blood specimens, For professional use only.

INTRODUCTION

VL is a severe disease with high mortality, endemic in 88 countries including 17 developed nations (1,2). A serious problem in much of the world including Brazil, China, East Africa, India and areas of the Middle East, leishmaniasis is also endemic in the Mediterranean region including southern France, Italy, Greece, Spain, Portugal and Northern Africa. In areas where leishmaniasis is endemic, recent migration patterns of people, vectors (sandfly) and reservoirs (dogs) have led to the urbanization of VL (3). In Southern Europe, VL has become the leading opportunistic infection in AIDS patients (4,13). VL is caused by members of the Leishmania donovani complex and canines have been identified as the major reservoir for transmission (5-8). Sero diagnosis has been widely utilized to establish infection because anti-leishmanial antibody titers are high during acute disease. The preferred method of diagnosis in a laboratory situation is by ELISA, although fluorescent antibody (IFAT) or direct agglutination tests (DAT), both utilizing whole parasite, are still widely used (9-11). These tests are highly cross-reactive with trypanosomes and mycobacteria. In addition, the whole parasite preparations used are unstable and variable in quality. This rapid assay is for the qualitative determination of antibodies to a recombinant antigen specific for Visceral Leishmaniasis (12) caused by parasite members of L. donovani.

TEST PRINCIPAL

Pratham® Kala Azar Antibody Test Device utilizes the principle of Immunochromatography, a two site immunoassay on a membrane. As the test sample flows through the membrane assembly of the device, the colored Protein A-colloidal gold conjugate complexes with the antibody in the sample. The complex moves further on the membrane to the test region where it is immobilized by the rK39 recombinant VL antigen coated on the membrane leading to the formation of a colored band which confirms a positive teat result. Absence of this colored band in the test region indicates a negative test result. The unreacted conjugate and unbound complex if any move further on the membrane and are subsequently immobilized by the Protein A coated on the membrane at the control region, forming a colored band. This control band serves as an internal control to validate the test results.

KIT COMPONENTS

1. Pouch contents: Test Cassette, Sample Dropper, Desiccant
2. Assay Buffer
3. Instruction for use

MATERIAL REQUIRED BUT NOT PROVIDED

Timer, Gloves, Micro Pipette, Tips & Centrifuge etc.

STORAGE AND STABILITY

The sealed pouches in the test kit may be stored between 2-30ºC till the duration of self life as indicated on the pouch. Do not freeze. Once the pouch is opened, test card must be used immediately.

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 for short duration. For long storage, freeze at -20ºC 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 of use.

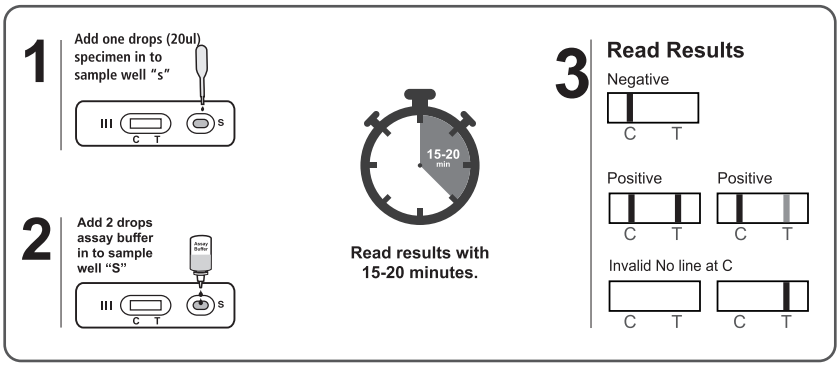
WARNING AND PRECAUTIONS

- 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 any where 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 one drop (20µl) of serum / plasma / whole blood into the sample well with the help of provided dropper in the kit or micro pipette.
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.

TEST PROCEDURE & INTERPRETATION OF RESULTS



Negative:

Appearance of only only one pink / purple line at control line region 'C' and No pink / purple line at test line region 'T' of the result window, indicates that specimens has no indicates presence of antibody of Kala Azar and result is negative.

Positive:

Appearance of two pink / purple lines, one at test region 'T' and other at control line region 'C' of the result window, indicates that specimen has indicates presence of antibody of Kala Azar and result is positive.

Invalid:

If there is no pink / purple line in the control line region 'C' of the result window, the result is invalid. This is due to determination of the test device or improper test procedure. Repeat the test with a new test 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.

PERFORMANCE CHARACTERISTICS

1. **Sensitivity:** In endemic areas, the sensitivity of the Pratham Kala Azae antibody test is 92% or better.
2. **Specificity:** Normal, healthy man and women do not have detectable levels of anti VL antibodies. The specificity of the test may vary with geographic location.
3. **Accuracy:** The reproducibility of the Kala Azar detect test strip was evaluated at 3 sites using a panel of confirmed VL sera. Positive, low/weak and normal serum samples were used. The samples were coded and tested at each site in triplicate for 3 consecutive days. Once the samples were decoded, the reading was in line with the ELISA titer. This data indicates that the reproducibility of the test is 100%.

LIMITATION OF THE TEST

1. This test will only indicate the presence of antibodies to the recombinant test antigen rK39 in patients with Visceral Leishmaniasis and should not be used as the sole criterion for the diagnosis of Leishmaniasis. This test alone must not be used for any clinical treatment decision. As with all diagnostic tests, all results must be considered with other clinical information available to the doctor.
2. If the result is negative and clinical symptoms persist, additional follow up testing using other clinical methods is recommended. A negative result does not preclude the possibility of Leishmaniasis.
3. A false positive result may occur. Confirmatory testing (such as by culture) is advised especially in cases where no symptoms exist.
4. Do not use serum samples containing any glycerol or other viscous materials. This will decrease the sensitivity of the assay.
5. Persons with advanced HIV infection or other immunocompromising diseases frequently have low or undetectable anti-Leishmanial antibodies.
6. This test may yield false positive results with samples from patients having malaria. The performance of this test has not been evaluated with L. infantum.
7. Certain Rheumatoid Factor (RF) positive sera may produce false positives results when Kala Azae detect is used.

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. Evans, T.G., I.A.B. Vasconcelos, J.N. Lima, et al. 1990. Am. J. Trop. Med. Hyg. (42)118-123.
2. Alvar J., R. Molina, M. San Andres, et al. 1994 Ann. Trop. Med. & amp; Parasit. 88(4) 371-8.
3. Allain, D.S., and I.G. Kagan. 1975. Am. J. Trop. Med. Hyg. (24) 232-236.
4. Badaro, R., S.G. Reed, and E.M. Carvallio. 1983. Am. J. Trop. Med. Hyg. 32(3) 480-484.
5. WHO. 1990. Control of the Leishmaniases, World Health Organization, Technical Report Series No. 793. Marsden, P.D. 1984. Rev. Inf. Dis. (6) 736-744.

6. Jeronimo S.M.B., R.M. Oliveira, S.Mackay, et al. 1994. Trans. R. Soc. Trop. Med. Hyg. 88(4) 368-386.
7. Berenguer, J., S. Moreno, E. Cercenado, et at. 1989. Ann. Intern. Med. (111) 129-132.
8. Ashford, D.A., R. Badaro, C. Eulalio, et at. 1993. Am. J. Med. Hyg. 48(1) 1-8.
9. Neogy, A.B., I. Vouldoukis, A.S. Otamires, et al. 1993. Am. J. Trop. Med. Hyg. (47) 772-777.

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:
ASTAM DIAGNOSTICS PVT. LTD.
Plot No. H-125, RIICO Indl. Area, Kaharani, Bhiwadi Extn.
Alwar, Rajasthan-301019 (INDIA)
For feedback/queries contact customer care : 011-27358101