ASTAM DIAGNOSTICS

PRODUCT INSERT

REF CHKD

PRATHAM® Chikungunya Antibody Test

A lateral flow chromatographic immunoassay for the qualitative detection of Chikungunya antibodies in human serum / plasma / whole blood

INTENDED USE

PRATHAM® Chikungunya Test is an in vitro diagnostic rapid test based on the principle of immunochromatography on a membrane, for simultaneous and differential detection of Chikungunya specific antibody (IgM/IgG) in human serum / plasma / whole blood for diagnosis of Chikungunya infection. For professional use only.

INTRODUCTION

Chikungunya is a rare viral infection transmitted by the bite of infected mosquitoes, predominantly Aedes aegypti mosquito. It is characterized by a rash, fever and severe joint pain (arthralgia) that usually lasts for three to seven days. The name is derived from the Makonde word meaning 'that which bends up' in reference to the stopped posture developed as a result of the arthritic symptoms of the disease. It occurs during the rainy season in tropical areas of the world, primarily in Africa, South-East Asia, southern India and Pakistan.1, 2 The symptoms are most often clinically indistinguishable from those observed in dengue fever. Indeed, dual infection of dengue and chikungunya has been reported in India. 3 Unlike dengue, hemorrhagic manifestations are relatively rare and most often the disease is a self-limiting febrile illness. Therefore, it is very important to clinically distinguish based on serological analysis and viral isolation in mice or tissue culture. An IgM immunoassay is the most practical lab test method.

TEST PRINCIPAL

PRATHAM® Chikungunya Test is a two site sandwich immunoassay based on the principle of immunochromatography on a membrane. Chikungunya (IgM/IgG) test is a three line test predispensed with anti human IgM at the test line region "M", anti human IgG/ protein-A at the test line region "G", and a protein ligand at control line region "C". When sample is added in sample well followed by sample running buffer, IgG/IgM antibodies if present in the sample reacts with gold conjugated with recombinant antigens of Chikungunya. This complex moves further up and reacts with the anti human IgG/IgM antibodies coated on the membrane leading to the formation of colored band at the IgM/IgG region. The appearance of colored band in the specific region is considered as positive result for that particular antibody. If the specimen does not contain any Chikungunya antibodies, no colored line will appear in either of the test line regions, indicating a negative test result. To serve as a procedural control, a colored line will always appear in the control line region confirming that the test has performed properly.

KIT COMPONENTS

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

MATERIAL REQUIRED BUT NOT PROVIDED

Timer, Gloves, Micropipette, tips & centrifuge etc.

STORAGE AND STABILITY

The sealed pouches in the test kit may be stored between 2-30ºC till the duration of shelf 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 to use.

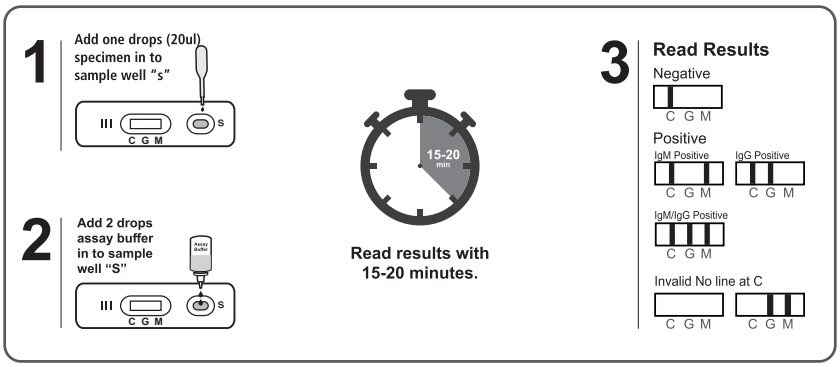
WARNING AND PRECAUTION

- 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 throw away used device, sample tube and tips any were 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 use another test.
4. Add one drop (20µl) of serum / plasma / whole blood into the sample well.
5. Add 2 drops of assay/running buffer into the sample well using provided buffer vial.
6. Interpret test results withing 15-20 minutes. Don't interpret results after 20 minutes.

INTERPRETATION OF RESULTS



Negative:
Appearance of 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 specimen has no indicates presence of antibody of Chikungunya and result is negative.

Positive:
Along with the control band, if the "M" band appears, the specimen is infected with IgM. If "G" band appears, the specimen is infected with IgG, If both "M" & "G" band appears, the specimen is infected with both IgM and IgG.

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 deterioration 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 and 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: Chikungunya (IgM/IgG): 98%
2. Specificity: Chikungunya (IgM/IgG): 97%
3. Accuracy: The results obtained by chikungunya test correlated very well when run in parallel and negative specimens. For the primary and secondary infection, the overall accuracy is 99.0%.
4. Precision: Repeatability and reproducibility (inter-assay and inter-lot) were evaluated on a number of negative and positive samples. no variations were found in the outcome of the different tests.

LIMITATION OF THE TEST

1. Chikungunya test is a in vitro diagnostic test. The test should be used for qualitative detection of Chikungunya IgM/IgG antibodies in serum or plasma specimens only. Neither the quantitative value not the rate of increase in antibody concentration can be determined by this qualitative test.
2. The test detects the presence of IgM / IgG antibodies to Chikungunya virus in the specimen and should bo tbe used as the sole criteria for the diagnosis of Chikungunya virus infection.
3. A negative result can occur if the quantity of IgM / IgG antibody present in the specimen is below the detection limit of the assay, or the antibody that are detected are not present during the stage of disease when sample was collected.
4. If the result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of Chikungunya infection.
5. The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy. Results from immunosuppressed patients should be interpreted with caution.

DISPOSAL

Consider all test 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.

BIBLOGRAPHY OF SUGGESTED READING

1. Ng KW, Chow A, Win MK, Dimatatc F, Neo HY, Lye DC, Leo Y S. Clinical features and epidemiology of Chikungunya infection in Singapore, Singapore Med J 2009;50(8) 785-790.
2. Planing M, Grywna K, van Esbroeck M, Emmerich P, Drosten C. Chikungunya fever in travelers returning to Europe from the Indian Ocean region 2006. Emerg Infect Dis 2008;14:416-22.
3. Lanciotti RS, Kosoy OL, Laven JJ, et al. Chikungunya virus in US travellers returning from India, 2006. Emerg Infect Dis 2007;13:7647.
4. Ikuko Aoyama, Kenji Uno, Takahiro Yumisashi, Tomohiko Takasaki, Chang-Kweng Lim, Ichiro Kurane, Tetsuo Kase and Kazuo Takahashi, A case of Chikungunya Fever Imported from India to Japan, follow-up of specific IgM and IgG antibodies over a 6-months period, Jpn.J.Infect. Dis., 63,65-66,2010.
5. N. Thamizh Selvam, P K S Nair, Salini Chandran, T N Venugopalan, N Jaya, Study on IgM antibodies in disease diagnosis and treatment evaluation in Chikungunya, Journal of Pharmaceutical and Biomedical sciences, 2010, 1(15).

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		

Manufactured By:
ASTAM DIAGNOSTICS PVT. LTD.
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Alwar, Rajasthan-301019 (INDIA)
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