ASTAM DIAGNOSTICS

PRODUCT INSERT

REF DAGT

PRATHAM® Dengue NS1 Ag Test Device

Rapid test for qualitative detection of Dengue NS1 Antigen in human serum / plasma

INTENDED USE

PRATHAM® Dengue NS1 Antigen Test Device is an in vitro diagnostic rapid test based on the principle of immunochromatography on a membrane, for the qualitative detection of Dengue NS1 antigen in human serum/plasma. For professional use only.

INTRODUCTION

Dengue is caused by any of the four distinct but antigenically related serotypes of flavivirus (DEN-V1, DEN-V2, DEN-V3 & DEN-V4) found largely in tropic and subtropic areas. The viruses are transmitted to human by mosquito Aedes aegypti and Aedes albopictus causing dengue fever with severe flu like symptoms. WHO estimates that 55-60 million cases of dengue fever occur worldwide each year, including a more severe form called the dengue hemmorraghic fever (DHF) and dengue shock syndrome (DSS) During primary infection the classical symptoms are sudden onset of fever, intense headache, myalgia, arthralgia and rash. Secondary infection is most common in many parts of South East and South America.

During Primary infection a Non Structural Protein (NS-1) levels are raised and can be detected in early clinical phase of the disease from day 1-9. NS-1 Ag appears in serum / plasma before the onset of IgM & IgG antibodies and its detection in suspected dengue patient can be used as an early marker for the disease.

TEST PRINCIPAL

PRATHAM® Dengue NS1 Ag Test Device is a two site sandwich immunoassay based on the principle of immunochromatography on a membrane. Nitrocellulose strip is predispensed with anti-dengue NS-1 antibodies at the test line region "T" and Goat anti rabbit IgG at control line region "C". When the sample is dispensed into the sample well (S) of the test device, comes in contact with the conjugate pad containing anti dengue NS-1 antibody-colloidal gold conjugate and rabbit IgG colloidal gold conjugate. Dengue NS-1 antigen if present, binds to the anti dengue NS-1 antibody gold conjugate making antigen antibody complex. This complex moves further on the membrane to the test region where it comes in contact with immobilized anti dengue NS-1 antibodies at the test line region "T" leading to the formation of a colored band confirming positive result for dengue NS-1 antigen. Absence of colored band at test line region "T" confirms a negative test result for dengue NS-1 antigen. 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. Instruction for use

MATERIAL REQUIRED BUT NOT PROVIDED

Blood collection tubes, syringes, lancing device, lancets, swabs, gloves and timer 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.

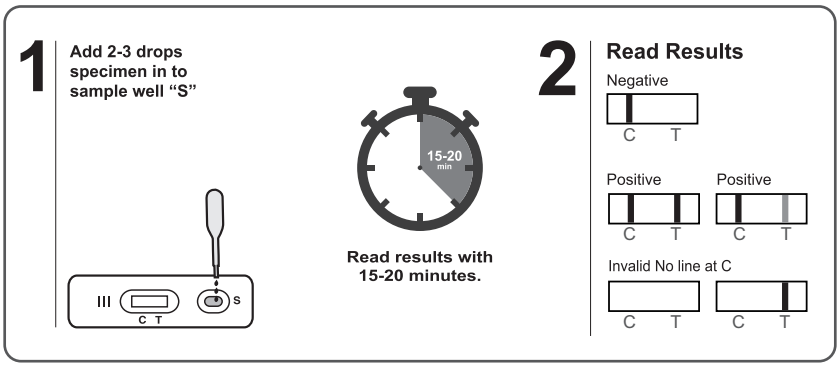
WARNING AND PRECAUTIONS

1. For professional use only, not to be used by the general public.
2. The test must be carried out by or under the direction of a registered medical practitioner or by a technician at the request of registered medical practitioner.
3. Bring all reagents and specimen to room temperature before use.
4. Do not pipette any material by mouth.
5. Do not eat, drink or smoke in the area where testing is done.
6. Use protective clothing and wear gloves when handling samples.
7. Use absorbent sheet to cover the working area.
8. Immediately clean up any spills with sodium hypochlorite.
9. Dispose off all the reagents and material used as if they contain infectious agent.
10. Neutralize acid containing waste before adding hypochlorite.
11. Do not use kit after the expiry date.
12. Do not mix components of one kit with another

TEST PROCEDURE

1. Bring the sealed pouch to room temperature, if the pouch of the test card is damaged discard the card and take a new one for the test. Open the pouch and remove the card. Label the card appropriately with patient identity. Once opened, the card must be used mmediately. Take out the test cards from the pouch by tearing from notch provided and place on flat surface.
2. Add 2-3 drops (about 50-75μl) of serum / plasma into the sample well (S) using dropper provided for NS-1 test.
3. Read results within 15-20 minutes. Do not read result after 20 minutes.
4. Discard used card in a biomedical waste container after interpreting the results.

INTERPRETATION OF RESULTS



Negative:
Appearance of only one colored band at control line region 'C'. The result should be considered negative for Dengue NS1.

Positive:
Appearance of colored bands at 'T' & 'C' regions indicate that specimen has Dengue antigen NS-1 and result is positive for Dengue infection.

Invalid:
Appearance of no colored band in the control line region C, the assay should be considered invalid regardless of any colored band in the T region. Repeat test with a new card.

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

Clinical Performance with positive and negative specimen: Samples from susceptible subjects were tested with DENGUE NS1 Ag Test Device and compared with commercially available test.

1. **Sensitivity: 98%**
2. **Specificity: 99%**
3. **Accuracy:** The results obtained by DENGUE NS1 Ag Test Device correlated very well when run in parallel with other commercially available tests, using known positive and negative specimens. For the primary and secondary infection, the overall accuracy is 99.3%.
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. Dengue NS1 Ag Test Device is a in vitro diagnostic test. The test should be used for qualitative detection of dengue antigen NS-1 in serum or plasma specimens only. Neither the quantitative value nor the rate of increase in dengue antigen concentration can be determined by this qualitative test.
2. The test detects the presence of Dengue NS1 antigen in the specimen and should not be used as the sole criteria for the diagnosis of Dengue virus infection.
3. A negative result can occur if the quantity of Dengue virus NS-1 antigen present in the specimen is below the detection limit of the assay.
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 Dengue infection.
5. Serological cross-reactivity across the flavivirus group (Dengue 1,2,3 & 4. St. Louis encephalitis West Nile virus, Japanese encephalitis and yellow fever viruses) is common. Positive results should be confirmed by other tests.
6. The continued presence or absence of antigen cannot be used to determine the success or failure of therapy.

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.

BIBLOGRAPHY OF SUGGESTED READING

1. Ampaiwan C, Wathanee C, Viroj P, Kanchana T, Sarapee L, Sutee Y. (2008). The use of Non structural protein 1 antigen for the early diagnosis during the febrile stage in patients with Dengue infection. J Paed Infect Dis;27:43-8.
2. Datta S, Wattal C. Dengue NS1 antigen detection: A useful tool in early diagnosis of Dengue virus infection. Indian J Med Microbiol 2010;28:107-10.
3. Sekaran SD, Lan EC, Mahesawarappa KB, Appanna R, Subramanium G. (2007). Evaluation of a Dengue NS1 capture ELISA assay for the rapid detection of dengue. J Infect Developing Countries;1:182-8.
4. Shu PY, Huang JH. (2004) Current advances in dengue diagnosis. Clinical and Diagnostic Laboratory Immunology;11:642-50.
5. Halstead SB, Selective primary health care: strategies for control of disease in the developing world: XI, Dengue, Rev. Infect. Dis. 1984;6:251-264.
6. Ruechusatsawat K, et al. Daily observation of antibody levels among dengue patients detected by enzyme linked immunosorbent assay (ELISA). Japanese J. Trop. Med. Hygiene 1984;22:9-12.

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
In-vitro diagnostic use	Keep away from Sunlight	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