

DENGUE DAY 1 TEST

Fight Dengue Early. Diagnose from Day 1

A complete dengue diagnostic test that detects early infection through NS1 Antigen and later-stage infection through IgM & IgG antibodies using human serum or plasma.

Salient Features

- First-Line Testing Kit for Dengue diagnosis
- Rapid visual test for Dengue NS1 Antigen & IgM & IgG Antibodies detection
- Diagnosis of both Primary & Secondary Infection
- Detects all 4 serotypes (Den-1, Den-2, Den-3 & Den-4) of Dengue Virus
- Highly Sensitive & Highly Specific
- Long Shelf Life 30 months at 2-30°C
- **Dengue NS1 Ag:**
Sensitivity: 96%
Specificity: 98%
- **Dengue IgM/IgG:**
Sensitivity: 95%
Specificity: 97%

First Indian Company

To Manufacture

DENGUE NS1 ANTIGEN

Detection Kit for RAPID TESTS

In collaboration with

ICGEB, New Delhi

Patented Product

Patent No.: 262648



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Dengue

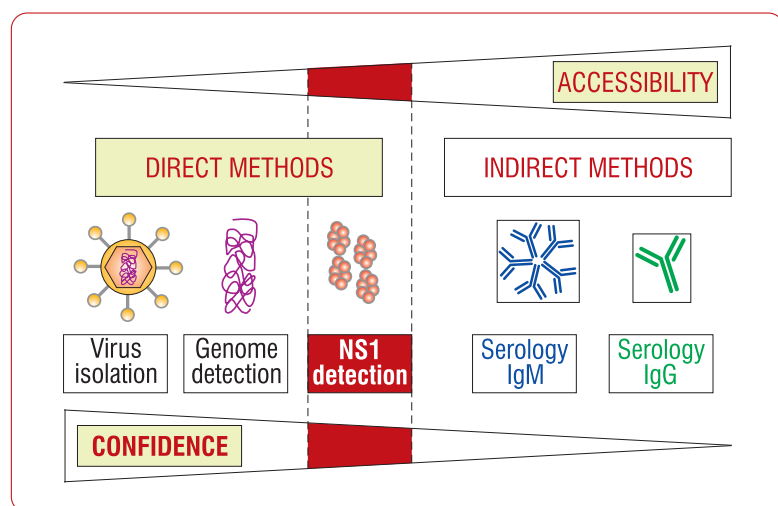
The Virus

Dengue is a viral infection transmitted by a mosquito (vector), the most important of which is *Aedes aegypti*.

The dengue virus belongs to the family of flaviviruses. There are four distinct but closely related serotypes (DEN 1-4) that co-circulate in many dengue endemic countries of the Asia Pacific region. A person can be infected by any one of all four serotypes. A second infection with a different dengue serotype is thought to be associated with increased risk of developing severe manifestations of Dengue.

Severe Dengue (previously known as Dengue hemorrhagic fever) affects most Asian and Latin American countries and has become a leading cause of hospitalization & death among children in these regions.

Figure 4.2 comparison of diagnostic tests according to their accessibility & confidence***



NS1 Ag detection is the method of choice being the direct method and having a balance relationship between the ease of use or accessibility of a diagnostic method and the confidence in the results of the test (Figure 4.2).

***source: Dengue Guidelines for Diagnosis, Treatment, Prevention & Control, New edition: 2009, WHO, Page No.: 92
http://whqlibdoc.who.int/publications/2009/9789241547871_eng.pdf

For Educational Purpose only.

Why Dengue DAY1 Test, Antigen & Antibody (Combi test) is more Reliable in Dengue Diagnosis

Study highlights that using dengue NS1 antigen detection in combination with IgM and IgG serology can significantly increase the sensitivity of acute dengue diagnosis & extends the possible window of detection to include very early acute samples & enhances the clinical utility of rapid immunochromatographic testing for dengue.

Source: Research Article - The Diagnostic Sensitivity of Dengue Rapid Test Assays Is Significantly Enhanced by Using a Combined Antigen and Antibody Testing Approach

www.plosntds.org/article/info%3Adoi%2F10.1371%2Fjournal.pntd.0001199

In an effort to "bridge" the diagnostic challenges posed by the initial period of viraemia & the delayed immunological responses, considerable interest is being given to the possibility of using combination of both NS1 Antigen & IgM tests to Diagnose Dengue.

Source: Page 6; Recommendations from the Asia Specific and the American Dengue prevention Boards

http://www.denguevaccines.org/sites/default/files/Dengue%20Diagnostics_Recommendations%20from%20the%20Asia-Pacific%20and%20the%20Americas%20DPBs.pdf

Dengue course of illness & approximate time-line of Primary and Secondary antibodies formations

Dengue is the most rapidly spreading mosquito-borne disease in the world. The key to handle dengue infection is its early recognition and understanding of the clinical problems during the different phases of the disease, leading to a rational approach to case management and good clinical outcome (Figure 2.1).

Dengue infection is the systematic and dynamic disease. After the incubation period, the illness begins abruptly and is followed by the 3 phases- febrile, critical and recovery (Figure 2.1).

NS1 ANTIGEN (Figure 4.1)

As can be observed from Figure 4.1, during early stage of disease, Antigen Detection can be used to diagnose the infection.

Detection of NS1 antigen is important for early and accurate diagnosis of dengue. NS1 Antigen can be detected from approximately Day 1 to Day 7 of fever setting in.

IgM ANTIBODIES (Figure 4.1)

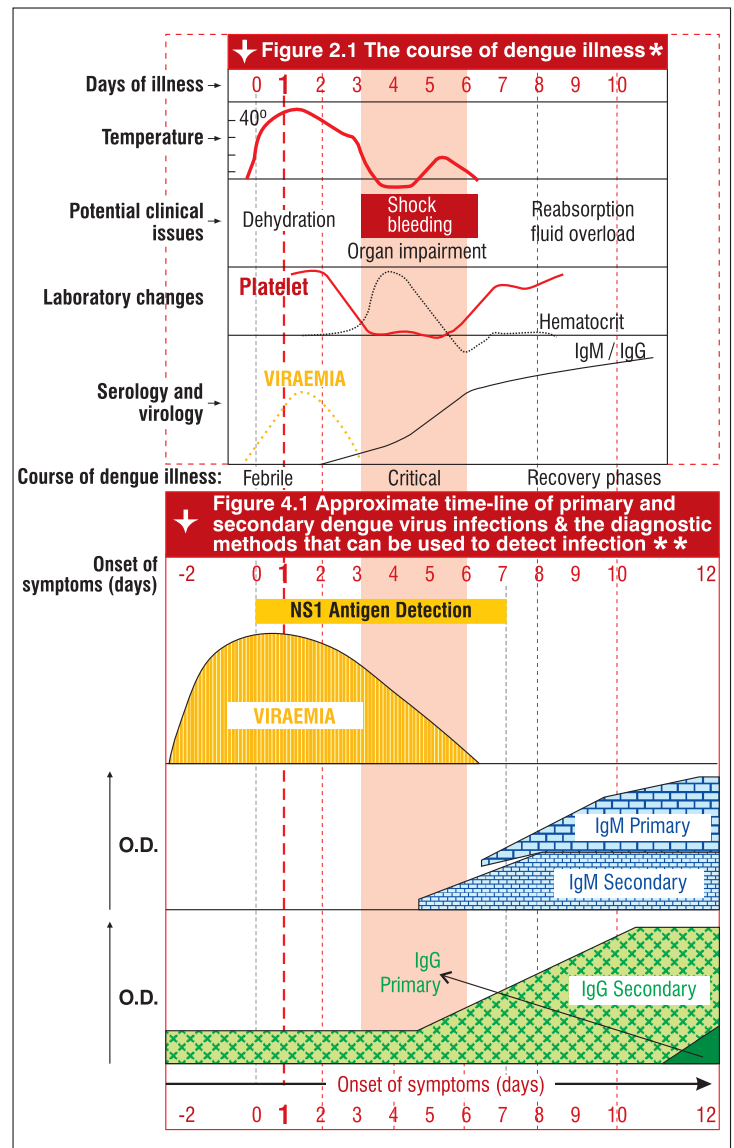
Antibody response to infection differs according to the immune status of the host. In primary Infection, IgM antibodies become detectable about 5-6 days after onset of disease. When the viremia declines, IgM level rises quickly to reach peak in about 2 weeks.

In Secondary infection IgM antibodies become detectable about 4-5 days and their levels are comparatively low.

IgG ANTIBODIES (Figure 4.1)

In primary infection, Antibody production of IgG will be at a lower level when compared to IgM. IgG antibodies are generally detectable at low levels in about 11-12 days and increase slowly and remain detectable after several months and probably even for life.

In Secondary infection, the IgG antibody level rises quickly reaching to peak in about 2 weeks after the onset of symptoms and may persists for years.



*source: Dengue Guidelines for Diagnosis, Treatment, Prevention & Control, New edition: 2009, WHO, Page No.: 25

**source: Dengue Guidelines for Diagnosis, Treatment, Prevention & Control, New edition: 2009, WHO, Page No.: 92

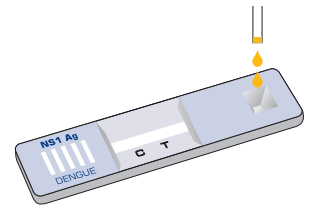
http://whqlibdoc.who.int/publications/2009/9789241547871_eng.pdf



Test Procedure

For Dengue NS1 Antigen Device

STEP-1 Add 2 drops (70 µl) of sample (serum/ Plasma) using Dengue Antigen Test sample dropper to the sample well of antigen device. Read result at 20 minutes



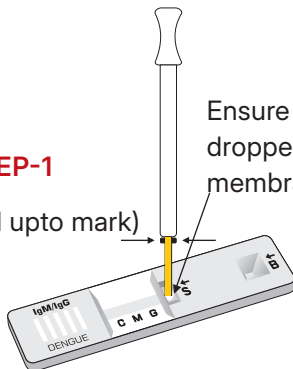
For Dengue IgM & IgG Device

Fill the Dengue Antibody sample dropper upto lower circular part with 10 µl specimen (serum/ plasma) and add the specimen to the sample well 'S' of antibody device.

STEP-1

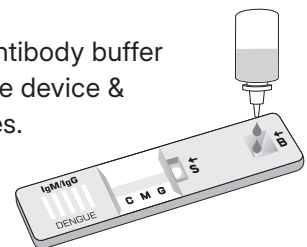
(Fill upto mark)

Ensure tip of the sample dropper touches the membrane of the device



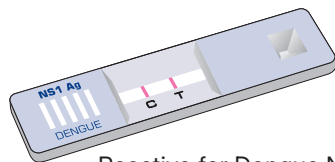
STEP-2

Add 2 drops of dengue antibody buffer to the buffer well 'B' of the device & Read results at 20 minutes.

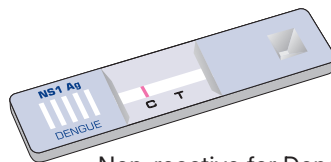


Result Interpretation

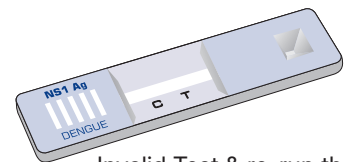
For Dengue NS1 Antigen Device



Reactive for Dengue NS1 Ag

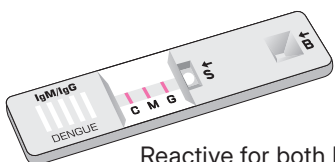


Non-reactive for Dengue NS1 Ag

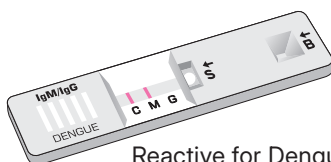


Invalid Test & re-run the test

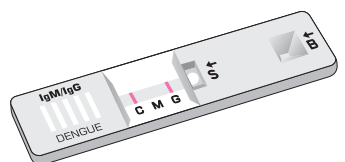
For Dengue IgM & IgG Device



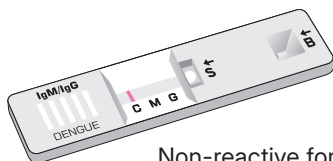
Reactive for both Dengue IgM & IgG antibodies



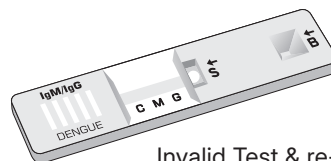
Reactive for Dengue IgM antibodies



Reactive for Dengue IgG antibodies



Non-reactive for Dengue antibodies



Invalid Test & re-run the test



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