Dengue can be Diagnosed & CONFIRMED by:

ELISA RANGE:
- NS1 ANTIGEN ELISA Test
- Dengue NS1 Ag Microlisa
- MAC ELISA Test
- Dengue IgM Microlisa
- GAC ELISA Test
- Dengue IgG Microlisa

Tests also Available:
RAPID RANGE:
- NS1 Antigen and IgM & IgG antibody Rapid Test
- Dengue DAY1 Test
- NS1 Antigen Rapid Test
- Advantage Dengue NS1 Ag Card

POCT TEST:
- NS1 Antigen (FINGER PRICK) Test
- Dengue NS1 Antigen FP

FLUORESCENCE BASED TEST:
- Dengue NS1 Antigen (FIA Test)
- Dengue NS1 Ag Quanti Card
- Dengue Antibody (FIA Test)
- Dengue IgM Quanti Card
- Dengue IgG Quanti Card
Dengue course of illness & approximate time-line of Primary and Secondary antibodies formation

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

**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.

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**NS1 Ag detection** is the method of choice being the direct method and have 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).

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**FIGURE 4.2 COMPARISON OF DIAGNOSTIC TESTS ACCORDING TO THEIR ACCESSIBILITY AND CONFIDENCE ***

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For Educational Purpose only.

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For Educational Purpose only.
**TEST PRINCIPLE**

Microwells pre-coated with Anti-Dengue NS1 Antibodies

Binding of Dengue NS1 antigen with Anti-Dengue NS1 antibody

Addition of Anti-Dengue NS1 antibody linked to HRPO (Enzyme Conjugate)

Addition of Chromogenic Substrate

Addition of Stop Solution and final reading of results at 450 nm / 630 nm

**TEST PROCEDURE**

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Prepare working conjugate solution</td>
</tr>
<tr>
<td>2</td>
<td>Add 100 µl working conjugate in each well</td>
</tr>
<tr>
<td>3</td>
<td>Cover the plate and incubate for 90 min. at 37°C</td>
</tr>
<tr>
<td>4</td>
<td>Wash 6 cycles</td>
</tr>
<tr>
<td>5</td>
<td>Prepare working substrate solution</td>
</tr>
<tr>
<td>6</td>
<td>Add 150 µl working substrate in each well</td>
</tr>
<tr>
<td>7</td>
<td>Incubate in dark for 30 min at room temperature. (20°C - 30°C)</td>
</tr>
<tr>
<td>8</td>
<td>Add 100µl Stop Solution and read result at 450 nm/630 nm.</td>
</tr>
</tbody>
</table>

**ELISA TEST**

Direct test method for Detecting infection with Dengue NS1 Ag

Excellent sensitivity against all the 4 serotypes of Dengue Virus Antigen

Significant reduction of Window period

Based on Direct Sandwich ELISA

No sample dilution is required

Long Shelf Life: 18 months at 2-8°C

Color Coded reagent

Convenient Packsize: 48 Tests & 96 Tests

**Sensitivity:** 99.5%

**Specificity:** 100%
**TEST PROCEDURE**

- Dilute sample (1:100)
  - sample 10 µl + sample diluent 1000 µl

- Add 100 µl control, calibrator & diluted sample in respective wells.

- Cover the plate and incubate for 60 min. at 37ºC

- Wash (5 cycles)

- Add 100 µl Enzyme Conjugate (Ready to use) in each well

- Cover the plate and incubate for 60 min. at 37ºC

- Wash (5 cycles)

- Prepare working substrate solution

- Add 100 µl working substrate in each well

- Incubate in dark for 30 min at room temperature.

- Add 50 µl Stop Solution and read result at 450 nm / 630 nm.

**TEST PRINCIPLE**

- Microwells pre-coated with Anti-Human IgM/ IgG Antibodies

- IgM/ IgG Antibodies bind with Anti-human IgM/ IgG Antibodies respectively

- Binding of Dengue Antigen conjugated with HRPO (Enzyme Conugate)

- Addition of Substrate

- Addition of Stop Solution and final reading of results at 450 nm / 630 nm

*The Preparation of working substrate solution mentioned above in the table is suggestive only, however working substrate solution can be prepared in any amount proportionately as per requirement of tests to be performed (from 5 tests to 96 tests as 3 calibrator, 1 negative control and 1 positive control are to be included in each run).*

**Principle:** "*Advance Capture*" ELISA

- Enzyme Conjugate (Ready to use), liquid stable for 18 months, no wastage
- Excellent Sensitivity against all 4 serotypes of Dengue
- High signal to noise ratio
- Color Coded reagents to monitor procedural steps
- Long shelf Life: 18 months at 2-8ºC
- Unique Break-away wells
- Convenient Packsize: 48 Tests & 96 Tests

**Sensitivity:** 99.13%

**Specificity:** 99.84%
RAPID TEST

Rapid visual test for the detection of Dengue NS1 Antigen and differential detection of IgM & IgG antibodies in Human Serum/Plasma

- First-Line Testing Kit for Dengue diagnosis
- Rapid visual test for Dengue NS1 Antigen and IgM & IgG Antibodies detection
- Diagnosis of both Primary & Secondary Infection
- Detects all 4 serotypes of Dengue Virus
- Highly Sensitive & Highly Specific
- Long Shelf Life 24 months at 2-30°C
- Convenient Packsize: 10 Tests, 30 Tests & 50 Tests

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 and extends the possible window of detection to include very early acute samples and 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

POCT (Point of Care) TEST

DENGUE NS1 ANTIGEN FP
Finger Prick quick visual test for the detection of Dengue NS1 Antigen in Human Whole Blood/ Serum/ Plasma

- Point of Care Test (POCT)
- Finger Prick quick visual test for detection of Dengue NS1 Antigen
- Results within 20 minutes
- From DAY1 of the fever, It detects all 4 serotypes of Dengue Virus
- Highly Sensitive & Highly Specific
- Individually pouches test device
- Longer Shelf Life: 24 Months At 2-30°C
- Patented Product: Patent No.: 262648
- Prompt Service Backup
- Convenient Packsize: 10 Tests
**DENGUE NS1 Ag Quanti Card**

Fluorescence immunoassay for qualitative detection of Dengue NS1 Antigen in Human Serum/Plasma

- Principle: Based on most advanced fluorescence immunoassay method
- Individually pouched test cartridge, each cartridge is precision engineered with embedded lot data.
- Results within 30 Minutes
- Sensitivity: 100%* & Specificity: 98.38%*
  (In comparison with ELISA Test)
- Long Shelf Life: 15 Months at 2-8°C
- Available Packsize: 24 & 48 Tests

*Source: https://doi.org/10.20546/ijcmas.2017.611.061, Table-3, Page-510

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**DENGUE IgG Quanti Card**

Fluorescence immunoassay for qualitative measurement of Dengue IgG Antibodies in Human Serum/Plasma

- Principle: Based on most advanced fluorescence immunoassay method
- Individually pouched test cartridge, each cartridge is precision engineered with embedded lot data.
- Results within 40 Minutes
- Sensitivity: 96.72%
- Specificity: 97.45%
  (In comparison with ELISA Test: Dengue IgM Microlisa)
- Long Shelf Life: 15 Months at 2-8°C
- Available Packsize: 24 & 48 Tests

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**DENGUE IgM Quanti Card**

Fluorescence immunoassay for the qualitative measurement of Dengue IgM Antibodies in Human Serum/Plasma

- Principle: Based on most advanced fluorescence immunoassay method
- Individually pouched test cartridge, each cartridge is precision engineered with embedded lot data.
- Results within 40 Minutes
- Sensitivity: 97.23%
- Specificity: 97.36%
  (In comparison with ELISA Test: Dengue IgG Microlisa)
- Long Shelf Life: 15 Months at 2-8°C
- Available Packsize: 24 & 48 Tests

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ICMED 13485

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