iQuant Analyzer

Fluorescence Immunoassay (FIA)

For Dengue NS1, IgM & IgG Tests

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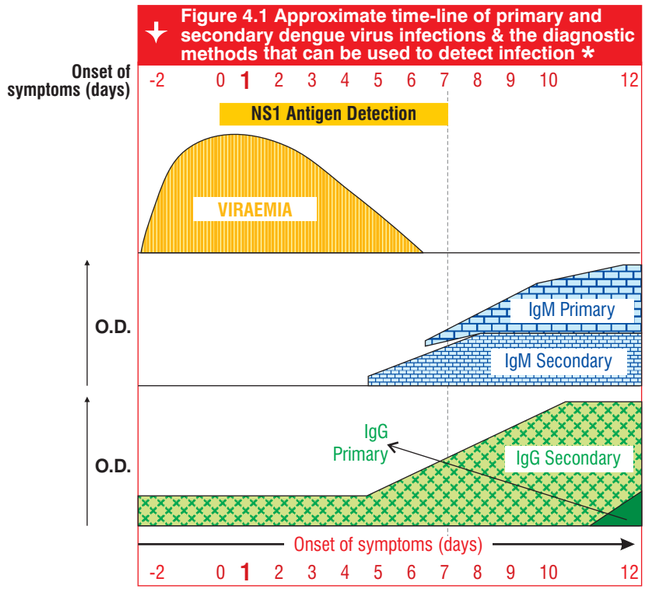
DENGUE FLUORESCENCE IMMUNOASSAY (FIA) TESTS

Dengue NS1, IgM & IgG tests by Fluorescence Immunoassay (FIA) on iQuant Analyzer



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

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 differes 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.

DENGUE NS1 Ag
QUANTI CARD

Fluorescence immunoassay (antigen-antibody) for the qualitative measurement of Dengue NS1 Antigen in Human Serum / Plasma

Available Packsize: 24 & 48 Tests

- **Principle: Based on most advanced fluorescence immunoassay method**
- **Individually pouched test cartridge, each cartridge is precision engineered with embeded lot data.**
- **From DAY1 of the fever, it detects all 4 serotypes of Dengue Virus**
- **Results within 30 Minutes**
- **Sensitivity: 100%* & Specificity: 98.38%* (In comparison with ELISA Test)**
- **Long Shelf Life: 15 Months At 2-8°C**

Evaluation and Comparison of Currently Available Fluorescence Immunoassay (FIA) Test with Rapid Immuno Chromatographic Test (ICT) considering NS1 ELISA as a Reference Test*

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Evaluation and Comparison of Currently Available Fluorescence Immunoassay (FIA) Test with Rapid Immuno Chromatographic Test (ICT) Considering NS 1 ELISA as a Reference Test

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ABSTRACT

Dengue is one of the rapidly emerging diseases globally. Early diagnosis can improve clinical outcome by ensuring close follow up, initiating appropriate supportive treatment and increasing awareness of hemorrhage and shock. Many diagnostic kits are available commercially. Amongst these gold standard test is IgM and IgG ELISA with seroconversion, but we can advice this test only after 5 days when the antibodies will start developing. Nonstructural glycoprotein 1 (NS-1) is considered to be a useful marker for early diagnosis of dengue, as this can be advised early. NS 1 ELISA is carried out only in institutional laboratories where technical expertisation as well as specific machines are available. So, for a routine laboratory with limited resources rapid ICT test is a better choice. In the present study the currently available Fluorescence immunoassay (FIA) test is evaluated and compared with rapid ICT considering NS 1 ELISA as a reference test. To evaluate the currently available fluorescence immunoassay test for detection of Dengue NS 1 antigen. To compare the currently available Fluorescence immunoassay (FIA) test for detection of Dengue NS 1 antigen with rapid ICT test and Microwell ELISA test. Cross sectional observational study. In this study, 200 samples from dengue suspected patients are tested for presence of NS 1 antigen by rapid ICT test. From these 50 positive and 50 negative samples are further retested by NS 1 ELISA and NS 1 by FIA. Results are analyzed and compared with each other. NS 1 ELISA is considered as a reference test and NS 1 Fluorescence immunoassay and rapid ICT as an index tests. Data is analyzed and sensitivity, specificity, positive predictive value and negative predictive value are derived for each test. FIA test is more specific and having positive predictive value of 97.43% which states that it is more reliable than rapid ICT. FIA is less time consuming and easy to perform whereas Microwell ELISA is time consuming and require highly technical expertise. NS 1 Microwell ELISA and FIA results are very much comparable with each other. Whereas false positive less with FIA and more with rapid ICT card test.

Keywords
Dengue, FIA, ELISA, ICT, NS 1 Antigen.

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> **FIA is less time consuming and easy to perform whereas Microwell ELISA is time consuming and require highly technical expertise.**
>
> **NS1 Microwell ELISA and FIA results are very much comparable in relation with sensitivity, specificity, positive predictive value, and negative predictive value.**
>
> **Hence for routine laboratories with limited resources one can use FIA test over Rapid ICT for early diagnosis of acute dengue infection.**

Table.2 Comparison of NS1 detection by FIA and NS1 Microwell ELISA*

ELISA → / FIA ↓	NS1 POSITIVE	NS1 NEGATIVE	Chi-square	P-value
NS1 POSITIVE	38	01	194	<0.0001 S
NS1 NEGATIVE	00	161		
Total (200)	38	162		

P-value S = significant.
From 50 positive samples by rapid ICT, 39 samples were positive and 11 were negative by FIA.

Table.3 Parameters of interest for Rapid ICT and FIA considering NS 1 ELISA as a reference test.*

	Rapid ICT	FIA
Sensitivity	100%	100%
Specificity	80.64%	98.38%
Positive predictive value	76%	97.43%
Negative predictive value	100%	100%

FIA test is more specific and having positive predictive value of 97.43% which states that it is more reliable than rapid ICT.

*Source: https://doi.org/10.20546/ijcmas.2017.611.061, Page- 506-513

DENGUE IgM
QUANTI CARD

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

Available Packsize: 24 & 48 Tests

- **Principle: Based on most advanced fluorescence immunoassay method**
- **Individually pouched test cartridge, each cartridge is precision engineered with embeded lot data.**
- **It detects all 4 serotypes of Dengue Virus**
- **Results within 40 Minutes**
- **Sensitivity: 96.72% & Specificity: 97.45% (In comparison with ELISA Test: Dengue IgM Microlisa)**
- **Long Shelf Life: 24 Months At 2-8°C**

DENGUE IgG
QUANTI CARD

Fluorescence immunoassay for the 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 embeded lot data.**
- **It detects all 4 serotypes of Dengue Virus**
- **Results within 40 Minutes**
- **Sensitivity: 97.23% & Specificity: 97.36% (In comparison with ELISA Test: Dengue IgG Microlisa)**
- **Long Shelf Life: 24 Months At 2-8°C**

Available Packsize: 24 & 48 Tests

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