e-ISSN: 0976-822X, p-ISSN:2961-6042

Available online on http://www.ijcpr.com/

International Journal of Current Pharmaceutical Review and Research 2026; 18(2); 617-620

Original Research Article

Original Research article: Study of Evaluation of a Novel Commercial Rapid Test for Early Detection of Acute Dengue Infection

Ashish Bhalsod[1], Kaushik Tilwani[2], Shreyaskumar N. Shah[3]

[1]Associate Professor, Department of Medicine, Dr Kiran C. Patel Medical College and Research Centre, Bharuch, Gujarat, India

[2]Assistant Professor, Department of Medicine, S.B.K.S. & MIRC, Sumandeep Vidyapeeth, Piparia, Vadodara, Gujarat, India

[3]Professor & Head, Department of Dentistry, Dr Kiran C. Patel Medical College and Research Centre, Bharuch, Gujarat, India

Received: 01-11-2025 / Revised: 15-12-2025 / Accepted: 21-01-2026

Corresponding author: Dr. Shreyaskumar N. Shah

Conflict of interest: Nil

Abstract

Introduction: The emerging pattern and the increasing trend in the incidence of dengue infection are of great concern as there is no specific treatment of dengue, and most forms of therapy are supportive in nature. We conducted a study to evaluate a newly available commercial rapid immunochromatographic test for the early diagnosis of dengue infection. This test is designed to simultaneously detect dengue NS1 antigen and IgM antibody.

Materials and Methods: This study was carried out in the Department of Microbiology of our institute and included 300 clinically suspected dengue cases. Screening for dengue infection was performed using a rapid immunochromatographic test (ICT) designed to detect both dengue NS1 antigen and IgM antibody (Advantage Dengue NS1 Ag and Ab Combi Card). In addition, all samples were tested for dengue-specific IgM antibodies using ELISA.

Results: Of the 300 clinically suspected dengue cases, 88 samples were found to be positive by rapid immunochromatographic testing. Among these positive cases, 67 showed NS1 antigen positivity, whereas 21 were positive for IgM antibodies. All samples were subsequently analyzed using IgM ELISA.

Conclusion: We would like to conclude that usefulness of NS1 antigen–based diagnostic methods for the early diagnosis of acute dengue virus infection. Rapid immunochromatographic tests enable prompt detection of both dengue NS1 antigen and IgM antibodies. Detection of NS1 antigen during the symptomatic phase of illness represents a significant advancement in the early diagnosis of dengue fever. The Dengue NS1 antigen strip, as a rapid diagnostic test for early dengue virus infection, demonstrated high sensitivity and specificity and is therefore suitable as a first-line diagnostic tool, particularly in field settings.

Keywords: ELISA, Rapid test, Dengue, IgM.

DOI: 10.25258/ijcpr.18.2.98

Introduction

Dengue virus is a mosquito-borne virus of the family Flaviviridae and genus Flavivirus, with four serotypes responsible for human infection. Clinical presentation ranges from mild febrile illness to severe dengue hemorrhagic fever. [1] It is an enveloped, positive-sense, single-stranded RNA virus with an approximately 11 kb genome encoding three structural proteins (C, M, and E) and seven non-structural proteins, including NS1. [2] Early diagnosis is essential for patient management and is likely to gain further importance with the future availability of antiviral therapies. [3] NS1, a highly conserved non-structural glycoprotein, plays a critical role in viral replication, although its precise function remains unclear. During acute infection, NS1 is expressed intracellularly, transported to the cell surface, and released into circulation as a hexameric protein detectable in patient serum. [4–7] Timely diagnosis is crucial for outbreak prediction and implementation of vector control measures. Confirmatory diagnosis can be made by virus isolation, RT-PCR, or serological detection of dengue-specific IgM and IgG antibodies. [5,8] However, molecular and culture-based methods are expensive and time-consuming, limiting their widespread use. Therefore, detection of dengue antigens or antibodies remains the most practical

diagnostic approach. NS1 antigen detection serves as an early marker of dengue infection due to its group- and type-specific epitopes and prolonged presence in blood, making it valuable for rapid diagnosis in the early phase of illness. [6,8,9]

Materials and Methods

This Retrospective Study was conducted at Department of Medicine of Dr Kiran C Patel Medical College and Research Centre and attached Civil Hospital, Bharuch, Gujarat from June 2025-Dec 2025. Patients suspected of dengue were defined as those presenting with acute febrile illness along with one or more features such as rash, bleeding manifestations, leukopenia, or thrombocytopenia, and were evaluated according to WHO criteria for probable dengue infection. [10]

Blood samples were collected from clinically suspected dengue cases attending Civil Hospital, Bharuch, and Gujarat between June 2025-Dec 2025.

Serum was separated and tested for dengue infection using a rapid immunochromatographic test capable of detecting both NS1 antigen and IgM antibody (Advantage Dengue NS1 Ag and Ab Combi Card). All samples were also tested using dengue IgM antibody capture ELISA.

The rapid immunochromatographic assay, which provides results within 20 minutes, consists of two separate devices: one for detection of dengue NS1 antigen and another for detection of dengue IgM antibodies. The NS1 device contains a control line (C) and a test line (T) coated with anti-dengue NS1 antibodies. In the presence of NS1 antigen, antigen–antibody complexes form and migrate along the membrane to produce a visible pink line at the test region. The IgM device contains a control line (C) and an IgM test line (M) coated with anti-human IgM.

Dengue-specific IgM antibodies in the sample bind to dengue antigen–coated particles and are captured at the test line, producing a red-colored band. The intensity of the test line varies with the concentration of antigen or antibody present, and the appearance of any visible colored band in the test region was considered positive. A visible control line in each device confirmed proper test performance.

All samples were subsequently evaluated using IgM capture ELISA supplied by the National Institute of Virology, Pune, which served as the reference standard. The ELISA procedure was performed according to the manufacturer's instructions, and optical density was measured at 450 nm. The OD values were proportional to the concentration of dengue-specific IgM antibodies, and samples with OD values greater than four times that of the negative control were interpreted as positive.

Results

Table 1: Comparison of Rapid ICT and IgM ELISA for Dengue Diagnosis

Parameter	Number of Cases
Total suspected dengue patients	300
Rapid ICT positive (NS1 and/or IgM)	88
IgM ELISA positive	53

Rapid ICT results were validated using IgM capture ELISA as the reference standard.

Table 2: Gender-wise Distribution of Rapid Test–Positive Dengue Cases

Sex	Number of Positive Cases
Male	53
Female	35
Total	**88**

Among the 88 rapid ICT–positive patients, a higher proportion were males compared to females.

Table 3: Age and Sex Distribution of Dengue-Positive Cases

Age Group (years)	Male (n=53)	Female (n=35)	Total
0–12	14	8	22
13–20	16	6	22
21–40	22	18	40
>40	1	3	4
Total	**53**	**25**	**88**

The majority of dengue-positive cases were observed in the 21–40 year age group.

Table 4: Distribution of Rapid ICT Positivity Pattern

Test Result Pattern	Number of Cases
NS1 antigen alone	49
IgM antibody alone	21
Both NS1 and IgM	18
Total ICT positive	**88**

Out of the total 88 ICT-positive cases, 53 were confirmed positive by IgM ELISA.

Table 5: Co-existing Infections among Dengue-Positive Patients

Parameter	Number of Cases
Total confirmed dengue cases	88
Dengue cases with associated malaria infection	40
Dengue cases with associated Widal test positivity	4

Table 6: Comparison of IgM Detection by Rapid ICT and ELISA

Result	IgM Rapid ICT	IgM ELISA
Negative	261	251
Positive	39	49
Total	300	300

This table compares IgM detection results between the rapid immunochromatographic test (ICT) and IgM ELISA for all suspected dengue cases. (Table 6)

Discussion

With the increasing incidence of dengue infection, the early diagnostic confirmation of dengue infection in patients allows for timely clinical intervention, etiological investigation, and disease control. Hence, diagnosis of dengue disease during the acute phase should be a priority and is a public health concern. Several approaches have been applied for laboratory diagnosis of dengue virus infection.

These methods include detection of the virus (by cell culture, immunofluorescence), detection of virus antigen (by enzyme-linked immunosorbent assay [ELISA]), detection of anti-dengue virus antibody (by hemagglutination inhibition [HI], complement fixation test [CF], neutralization tests, ELISA), and detection of virus nucleic acid (by real-time reverse transcription-polymerase chain reaction [RT-PCR]).

In our study, males were more frequently affected than females. Among the 88 dengue-positive patients, 40 had co-infection with malaria, and 4 tested positive by the Widal test (Table 4). Malaria is often observed alongside dengue due to their shared mode of transmission.

We employed two diagnostic methods for the early detection of dengue during the acute phase of illness. The dengue NS1 antigen strip—the first ICT developed for detection of NS1 across all dengue virus serotypes—is a rapid, convenient, and easy-to-use test, providing results within 15 minutes, even for borderline cases. In our study, of the 88 ICT-positive cases, 88 were positive for NS1 antigen by rapid ICT, whereas only 53 were confirmed by IgM ELISA. This indicates that NS1 antigen is a more reliable marker than IgM for early infections, particularly within the first four days of fever.

The rapid test requires minimal laboratory equipment, with only a microcentrifuge needed for serum separation. This makes it especially useful for screening and early diagnosis in resource-limited or peripheral healthcare settings. By enabling faster detection, the test can facilitate timely initiation of first-line management and provide significant support to healthcare providers, particularly in rural areas.

Conclusion

We would like to conclude that usefulness of NS1 antigen–based diagnostic methods for the early diagnosis of acute dengue virus infection. Rapid immunochromatographic tests enable prompt detection of both dengue NS1 antigen and IgM antibodies. Detection of NS1 antigen during the symptomatic phase of illness represents a significant advancement in the early diagnosis of dengue fever. The Dengue NS1 antigen strip, as a rapid diagnostic test for early dengue virus infection, demonstrated high sensitivity and specificity and is therefore suitable as a first-line diagnostic tool, particularly in field settings.

References

1. Gubler DJ, Meltzer M. Impact of dengue/dengue hemorrhagic fever on the developing world. Adv Virus Res. 1999; 53:35–70.
2. World Health Organization. Handbook of the World Health Organization. Geneva: WHO; 2000. pp. 1–84. (Dengue haemorrhagic fever: diagnosis, treatment and control).

3. Innis BL. In: Exotic Viral Infections. Porterfield JS, editor. London: Chapman & Hall Medical; 1995. pp. 103–140. (Dengue and dengue haemorrhagic fever).
4. Blacksell SD, Mammen MP, Thongpaseuth S, Gibbons RV, Jarman RG, Jenjaroen K, Nisalak A, Phetsouvanh R, Newton PN, Day NP. Evaluation of the Panbio dengue virus nonstructural 1 antigen detection and immunoglobulin M antibody enzyme-linked immunosorbent assays for the diagnosis of acute dengue infections in Laos. Diagn Microbiol Infect Dis. 2008; 60:43–49. doi: 10.1016/j.diagmicrobio.2007.07.011.
5. Dussart P, Labeau B, Lagathu G, Louis P, Nunes MR, Rodrigues SG, Storck-Hermann C, Cesaire R, Morvan J, Flamand M, Baril L. Evaluation of an enzyme immunoassay for detection of dengue virus NS1 antigen in human serum. Clin Vaccine Immunol. 2006; 13:1185–1189.
6. Kumarasamy V, Chua SK, Hassan Z, Wahab AH, Chem YK, Mohamad M, et al, Evaluating the sensitivity of a commercial dengue NS1 antigen capture ELISA for early diagnosis of acute dengue virus infection. Singapore Med J 2007; 48: 669-73.
7. Kumarasamy V, Wahab AH, Chua SK, Hassan Z, Chem YK, Mohamad M, et al, Evaluation of a commercial dengue NS1 antigen – capture ELISA for laboratory diagnosis of acute dengue virus infection. J virol methods 2007; 140: 75-9.
8. Das D, Mongkolanngkoon S, Suresh Mr. Super induction of dengue virus NS1 protein in E coli. Protein Expr purif 2009; 66: 66-72.
9. World Health Organization – dengue hemorrhagic fever: Diagnosis, Treatment Prevention and control 2nd ed. Geneva: WHO, 1997.