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Performance Evaluation of a Dengue IgG/IgM and NS1 Rapid Test Device for Profesional in Vitro Diagnostic Use in Whole Blood/Serum/Plasma

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Abstract

Objective: The objective of this evaluation report was to determine the reliability and performance of the All Test Dengue Combo Rapid Test Cassette, which is a qualitative test for the detection of NS1 antigen, IgG and IgM antibodies of Dengue virus in human whole Blood, serum or plasma.

Method: Run a rapid in vitro diagnostic test device for detection of Dengue IgG/IgM and NS1 in Whole Blood/Serum/Plasma whose clinical samples were compared with the leading commercial ELISA test for Dengue IgG/IgM and NS1 to verify its performance.

Results: The results demonstrated that the relative sensitivity of the Dengue NS1 Rapid Test Cassette (Whole Blood/Serum/Plasma) was 95.8%, and the relative specificity was 96.1%. The overall relative sensitivity for the primary and secondary infection of the Dengue Rapid Test (Whole Blood/Serum/Plasma) was 94.3%, the relative specificity was 99.1%, and the relative accuracy was 98.3%.

Conclusion: The Dengue Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of NS1 antigen, and IgG and IgM antibodies of Dengue virus in human whole blood, serum or plasma. The test utilizes a combination of NS1 antigen, IgG and IgM antibodies of the Dengue virus in human whole blood, serum or plasma.

Keywords: Dengue virus; NS1 Antigen Test; IgG; IgM Antibody Test

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Introduction

Dengue is a mosquito-borne viral disease that has rapidly spread to all regions of World Health Organization (WHO) in recent years. It is a flavivirus, transmitted by the Aedes aegypti and Aedes albopictus mosquitoes. Dengue virus is widely distributed throughout the tropical and subtropical areas of the world [1] and causes up to 100 million infections annually [2]. Classic Dengue infection is characterized by a sudden onset of fever, intense headache, myalgia, arthralgia and rash.

Primary Dengue infection causes IgM antibodies to increase to a detectable level in 3 to 5 days after the onset of fever. IgM antibodies generally persist for 30 to 90 days [3]. Most Dengue patients in endemic regions have secondary infections [4], resulting in high levels of specific IgG antibodies prior to or simultaneous with IgM response [5]. Therefore, the detection of specific anti-Dengue IgM and IgG antibodies can also help to distinguish between primary and secondary infections. NS1 is one of seven Dengue Virus non-structural proteins which are thought to be involved in viral replication. NS1 exists as a monomer in its immature form but is rapidly processed in the endoplasmic reticulum to form a stable dimer. A small amount of NS1 remains associated with intracellular organelles where it is thought to be involved in viral replication. The rest of NS1 is found either associated with the plasma membrane or secreted as a soluble hexadimer. NS1 is essential for viral viability but its precise biological function is unknown. Antibodies raised in response to NS1 in viral infection can cross react with cell surface antigens on epithelial cells and platelets and this has been implicated in the development of Dengue Hemorrhagic fever.

Currently there is no specific medicine to treat dengue. Once a fever is developed or the occurrence of symptoms, timely antibody or antigen detection is the most effective way to diagnose infection. The detection device with high sensitivity and specificity can ensure the accuracy of the result.

Material and Method

Principle of Dengue IgG/IgM Rapid Test (Whole Blood/Serum/Plasma)

The Dengue IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of Dengue antibodies in whole blood, serum, or plasma. This test consists of two components; an IgG component and an IgM component. In the IgG component, anti-human IgG is coated in the IgG test line region. During testing, the specimen reacts with Dengue antigen-coated particles in the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in the IgG test line region. If the specimen contains IgG antibodies to Dengue, a colored line will appear in the IgG test line region. In the IgM component, anti-human IgM is coated in the IgM test line region. During testing, the specimen reacts with anti-human IgM. Dengue IgM antibodies, if present in the specimen, react with the anti-human IgM and the Dengue antigen-coated particles in the test cassette. This complex is captured by the anti-human IgM, forming a colored line in the IgM test line region.

Therefore, if the specimen contains Dengue IgG and/or IgM antibodies, a colored line will appear in the IgG and/or IgM test line region. If the specimen does not contain Dengue antibodies, no colored line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

IgG and IgM Positive: Three colored lines appear. One colored line should be in the control line region (C), and two colored lines should appear in the IgG test line region and IgM test line region. The color intensities of the lines do not have to match. The result is positive for IgG & IgM antibodies indicated the end stage of primary Dengue infection and early stage of secondary Dengue infection.

IgG Positive: Two colored lines appear. One colored line should be in the control line region (C), and a colored line appears in IgG test line region. The result is positive for Dengue virus specific-IgG and is probably indicative of secondary Dengue infection.

IgM Positive: Two colored lines appear. One colored line should be in the control line region (C), and a colored line appears in the IgM test line region. The result is positive for Dengue virus specific-IgM antibodies and is indicative of primary Dengue infection. The test result is obtained in 10 minutes or less after applying the sample to the test device.

Principle of Dengue IgG/IgM Rapid Test (Whole Blood/Serum/Plasma)

The Dengue NS1 Rapid Test (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of Dengue NS1 antigen in whole blood, serum, or plasma. During testing, the specimen reacts with Dengue antibody conjugate in the test cassette. The Gold-antibody conjugate will bind to the Dengue antigen in the specimen sample which in turn will bind with Anti-Dengue NS1 coated on the membrane. As the reagent moves across the membrane, the Dengue NS1 antibody on the membrane will bind the antibody-antigen complex causing the colored line to form at the test line region of the test membrane. The intensity of the lines will vary depending upon the amount of antigen present in the sample. The appearance of the colored line in the test region should be considered as a positive result.

NS1 Positive: Two colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (NS1). The test result is obtained in 10 minutes or less after applying the sample to the test device.

Sensitivity and Specificity Results

The Dengue Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) has passed a seroconversion panel and was compared with a leading commercial Dengue Ag ELISA test using clinical specimens for Dengue NS1. The Dengue test has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. Results were confirmed by a leading commercial Dengue ELISA test for IgG and IgM.

The results show that the relative sensitivity of the Dengue NS1 Rapid Test Cassette (Whole Blood/Serum/Plasma) was 95.8% and the relative specificity was 96.1%. (See Table 1 Dengue NS1) (**Tables 1-4**).

Table 1. Dengue NS1.

Method		ELISA		Total Results
Dengue NS1 Rapid Test (Whole Blood/Serum/Plasma)	Results	Positive	Negative	
	Positive	137	8	145
	Negative	6	200	206
Total Results		143	208	351

Relative Sensitivity: 137/143*100%=95.8% (95%CI*: 91.1%~98.4%)

Relative Specificity: 200/208*100%=96.1% (95%CI*: 92.6%~98.4%)

Accuracy: (137+200)/(137+6+8+200)*100%=96.0%(95%CI*:93.4%~97.8%).

Table 2. Dengue Primary Infection for IgM/IgG test Results (Dengue IgG/IgM).

Method			ELISA		
Dengue NS1 Rapid Test (Whole Blood/Serum/Plasma)	Results		Positive		Negative
			IgM	IgG	
	Positive	IgM	20	0	0
		IgG	4	0	0
	Negative		0	0	0
Relative Sensitivity			83.3%	/	/

Table 3. Dengue Secondary Infection for IgM/IgG test Results (Dengue IgG/IgM).

Method			ELISA		
Dengue NS1 Rapid Test (Whole Blood/Serum/Plasma)	Results		Positive		Negative
			IgM	IgG	
	Positive	IgM	46	1	0
		IgG	18	63	0
	Negative		0	0	0
Relative Sensitivity			71.9%	98.4%	/

Table 4. Non-Dengue Infection for IgM/IgG test result (Dengue IgG/IgM).

Method			ELISA		
Dengue NS1 Rapid Test (Whole Blood/Serum/ Plasma)	Results		Positive		Negative
			IgM	IgG	
	Positive	IgM	0	0	1
		IgG	0	0	3
	Negative		0	0	429
Relative Sensitivity			/	/	99.1%

Relative Sensitivity: (20+63)/ (24+64) =94.3% (95%CI*: 87.2%~98.1%);

Relative Specificity: 429/433=99.1% (95% CI*: 97.7%~99.7%);

Accuracy: (20+63+429)/ (24+64+433) =98.3% (95% CI*: 96.7%~99.2%).

Summary

All Dengue Combo Rapid Test Cassette (Whole Blood/Serum/ Plasma) kits developed by All Test tested in this evaluation performed well. The tests demonstrated excellent accuracy, sensitivity and specificity.

The results showed that the relative sensitivity of the Dengue NS1 Rapid Test Cassette was 95.8%, accuracy was 96.0% and the relative specificity was 96.1%. The overall relative sensitivity of Dengue IgG/IgM Rapid Test was 94.3%, the relative specificity was 99.1%, and the relative accuracy was 98.3%.

This laboratory evaluation could differ from the performance outside the laboratory due to the limited sample range and close monitoring that is carried out by professionals. From the results of the tested samples, it presents that the Dengue Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) developed by Hangzhou All Test Biotech Co., Ltd. meets the requirements of intended use.

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