Dengue Ns1 Ag Rapid Test

INTENDED USE

The Dengue NS1 Rapid Test is an immunochromatographic assay for the qualitative Detection of non-structural protein 1 (NS1) in human serum/plasma.

SUMMARY AND EXPLANATION OF THE TEST

Dengue is an acute viral disease, which is transmitted by *Aedes aegypti* mosquitoes. Dengue is characterized clinically by biphasic fever, rash and hematopoietic depression, and by constitutional symptoms such as malaise, arthralgia, myalgia and headache (1). Infrequently, more severe disease is seen, manifested by hemorrhage fever which may progress to lethal shock (2, 3). It is endemic in the tropics and subtropics, worldwide, where an estimated 100,000,000 cases occur annually (4). It has been estimated that about 50 to 100 million cases of Dengue Fever (DF) occur every year with about 250,000 to 500,000 cases of Dengue Hemorrhagic Fever (DHF). During 2002, more than 30 Latin American countries reported over 10,000,000 (DF) cases with large number of DHF cases. This has been followed by extensive epidemics of DHF in several parts of India during 2003 through 2005. In the Americas, the reported incidence has more than tripled from 1996 to 2002. The incidence of Dengue outbreak has been reported in Hawaii (5), and in Laredo, Texas. The potential for the virus to cause a severe disease has also resulted in the inclusion of this pathogen on the CDC "category A" list for potential biological warfare and bioterrorism agents. Dengue NS1 (non-structural) protein is a multimeric secreted protein that is believed to play a role in viral RNA replication. It is strongly immunogenic eliciting antibodies with complement fixing activity. NS1 antigen can be detected in circulating blood during acute Dengue infection. The Aspen Dengue NS1 Rapid Test detects NS1 antigen in serum samples following infection.

PRINCIPLE OF THE TEST

The Dengue NS1 Rapid Test is a qualitative, membrane based immunoassay for the detection of NS1 antigen in human serum/Plasma. The rapid test membrane is pre-coated with a NS1 specific antibody on the test line region and utilizes a separate control to assure assay flow and performance. During testing, the test sample is added directly to the sample region and the test is placed into a well containing 3 drops of buffer. The buffer and serum mix and interact with NS1-specific monoclonal antibodies conjugated to gold nanoparticles. The solution migrates upward on the membrane (via capillary action) to react with the anti-NS1 antibody on the membrane. If NS1 antigen is present, a red line will appear at the test line. The red line at the control region should always appear if the assay is performed correctly.

KIT CONTENTS

1. Dengue NS1 Test Device (individually pouched)
2. Buffer
3. Sample droppers
4. Product insert

KIT STORAGE AND PRECAUTIONS

The sealed pouch containing the test device and Buffer is designed to be stored at room temperature (22°C-30°C) till the expiry. Exposure to the temperatures over 30°C can impact performance of the test. The kit should not be frozen. The test should be used within 15 minutes after removal from the pouch to prevent exposure to humidity (5 minutes in high humidity areas).

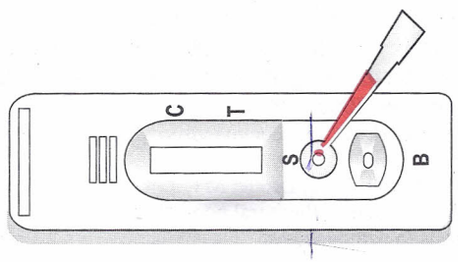
SPECIMEN COLLECTION AND STORAGE

- Human serum /Plasma must be used with this assay and usual precautions for venipuncture should be observed.
- Testing should be performed as soon as possible after collection. Do not leave serum/Plasma at room temperature for prolonged periods.
- The samples may be stored at 2-8°C for up to 7 days or frozen at -20°C or lower for up to 30 days.

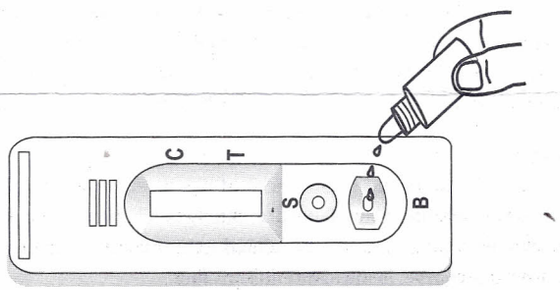
TEST PROCEDURE

Remove the Dengue NS1 Rapid test from the foil pouch and assure that all test serum samples are allowed to reach room temperature.

1. **Add 50µl** of **test sample** to the **Sample well (S)** by using a pipette (or 2 drops of sample by using provided sample dropper).

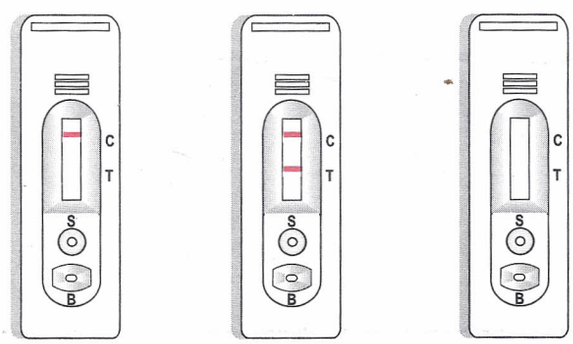


2. **Add 3 drops** **of buffer in buffer (B)well**



4. **Read the result** after **15 minutes.** Do not interpret results after 30 minutes.

INTERPRETATION OF RESULTS



Negative NS1(+) Invalid