One Step Dengue NS1 Ag Test

(Whole Blood/Serum/Plasma)

FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY

Intended Use

The One Step Dengue NS1 Ag Test is a rapid chromatographic immunoassay for the qualitative detection of dengue virus NS1 antigen in Whole Blood /Serum / Plasma to aid in the diagnosis of Dengue viral infection.

Summary

Dengue is transmitted by the bite of an Aedes mosquito infected with any one of the four dengue viruses. It occurs in tropical and sub-tropical areas of the world. Symptoms appear 3—14 days after the infective bite. Dengue fever is a febrile illness that affects infants, young children and adults. Dengue haemorrhagic fever (fever, abdominal pain, vomiting, bleeding) is a potentially lethal complication, affecting mainly children. Early clinical diagnosis and careful clinical management by experienced physicians and nurses increase survival of patients. One step Dengue NS1 Ag Test is a simple, visual qualitative test that detects dengue virus NS1 antigen in human Whole Blood/serum/plasma. The test is based on immunochromatography and can give a result within 15 minutes.

Principle

The One Step Dengue NS1 Ag Test is a qualitative membrane strip based immunoassay for the detection of dengue virus NS1 antigen in Whole Blood /Serum / Plasma. In this test procedure, anti-Dengue NS1 antibody is immobilized in the test line region of the device. After a Whole Blood /Serum / Plasma specimen is placed in the specimen well, it reacts with anti-Dengue NS1 antibody coated particles that have been applied to the specimen pad. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized anti-Dengue NS1 antibody. If the specimen contains dengue virus NS1 antigen, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain dengue virus NS1 antigen, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

Storage and Stability

- Store as packaged in the sealed pouch at room temperature or refrigerated (2-30℃ or 40-86℉). The test device is stable through the expiration date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.

Additional Special Equipment

Materials Provided

- Test devices
- Disposable specimen droppers
- Buffer (for whole blood only)
- Package insert

Materials Required But Not Provided

- Timer
- Centrifuge
- Specimen collection containers

Precautions

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- Handle all specimens as if they contain infectious agents.
- Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Follow standard biosafety guidelines for handling and disposal of potential infective material.
- Humidity and temperature can adversely affect results.

Specimen Collection and Preparation

1. The One Step Dengue NS1 Ag Test can be performed used on Whole Blood /Serum / Plasma.
2. To collect whole blood, serum or plasma specimens following regular clinical laboratory procedures.
3. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
4. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8℃ for up to 3 days. For long term storage, specimens should be kept below -20℃. Whole blood should be stored at 2-8℃ if the test is to be run within 2 days of collection. Do not freeze whole blood specimens.
5. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.