

**One step rapid Card Test for detection of NS1 Antigen to dengue virus in human Serum/Plasma**

**For In-Vitro Diagnostic Use only**

**ORDER INFORMATION**

Pack Size	REF
10 Tests	DENS 10
25 Tests	DENS 25

**CLINICAL SIGNIFICANCE**

Dengue virus, a virus belonging to the Flavivirus group of viruses, is one of the most significant mosquito-borne diseases in the world in terms of morbidity and mortality. Transmitted principally by the mosquito types *Aedes aegypti* and *Aedes albopictus*, the virus is found commonly throughout the tropic and subtropic regions of the world. There are four known serotypes of dengue. Symptoms of dengue fever include high fever, headache, muscle pain and skin rash. The complications often associated with this infection are dengue hemorrhagic fever or dengue shock syndrome.

Dengue NS1 Antigen Test provides an excellent methodology for specifically detecting Dengue NS1 antigen within up to 1 day of infection.

**PRINCIPLE**

ACCUCARE® ONE STEP DENGUE NS1 RAPID TEST is a qualitative immunoassay for the detection of NS1 antigen to dengue virus in human serum or plasma. The nitrocellulose membrane is pre-coated with NS1 specific antibody at Test region and separate control to assure assay flow and test performance. The specimen is added in sample well followed by assay buffer which will react with NS1 specific monoclonal antibodies conjugated to colloidal gold. This antigen-antibody complex move upward on the membrane via capillary action and will bind with Anti-Dengue NS1 which is pre-coated on the membrane. As the reagent moves across the membrane, the Dengue NS1 antibody on the membrane will bind with antigen-antibody complex and formed pinkish purple line at the test 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 pinkish purple line in the test region should be considered as positive result.

**CONTENTS**

Test Device, Desiccant  
Assay Buffer ,Instruction for Use (IFU)  
Disposable (Dropper) 10 µl

**STORAGE & STABILITY**

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed aluminum pouch until use. **DO NOT FREEZE.**
2. Do not use beyond the expiration date.
3. Do not use the test device/strip, if the pouch is damaged or seal is broken.

**PRECAUTIONS**

1. For professional In-vitro diagnostic use only.
2. Do not use after expiration date.

3. Do not eat, drink or smoke in the area where the specimens or kits are handled.
4. Handle all the specimens as potentially infectious. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens and tested device/strip.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
6. Read the Instruction for use carefully before performing the test.

**LIMITATIONS**

1. ACCUCARE® ONE STEP DENGUE NS1 RAPID TEST detects the presence of Dengue NS1 antigen and should not be used as the sole criteria for the diagnosis of Dengue virus infection.
2. Serological cross-reactivity across the Flavivirus group is common.
3. As with all diagnostic tests, all results must be correlated with other clinical findings. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result at any time does not preclude the possibility of an early infection of Dengue virus.
4. This is only a screening test. Therefore, isolation of virus, antigen detection in fixed tissues, RT-PCR and more specific alternative diagnosis method must be used in order to obtain a confirmation of dengue virus infection.

**SPECIMEN COLLECTION & PREPARATION**

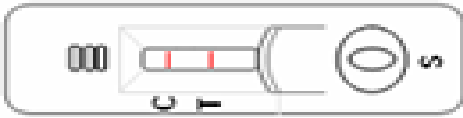
1. The ACCUCARE® ONE STEP DENGUE NS1 RAPID TEST can be performed using either serum or plasma.
2. Separate the serum or plasma from whole blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
4. 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.
5. If specimens are to be shipped, it should be packed in compliance with federal regulations for transportation of etiologic agents.

**PROCEDURE**

1. Allow test device, Assay Buffer and specimen equilibrates to room temperature (15-30°C) prior to testing.
2. Remove the test device from the aluminum foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
3. Place the test device on a clean and flat surface. Carefully dispense 1 drop (10 µl) of Serum/Plasma in the sample well "S" using the dropper provided.
4. After that add 1 drop (appx. 40 µl) of Assay Buffer in the sample well "S".
5. Allow reaction to occur and read the results at 15 minutes. Do not interpret the results after 20 minutes.

**INTERPRETATION OF RESULTS**

**1. POSITIVE**



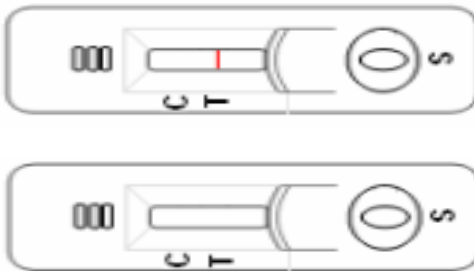
If two color lines appear, one at control region 'C' and other at test region 'T', the specimen is positive for Dengue NS1 antigen.

**2. NEGATIVE**



If only one color line appear at control region 'C' as the specimen is Negative for Dengue NS1 antigen.

**3. INVALID**



If no color line appear, at control region 'C' within the stipulated time then result is invalid. Repeat the test using a fresh Test Device/Strip.

**NOTE:** The intensity of the color band in the test line region will vary depending on the concentration of Dengue NS1 antigen present in the specimen. However, neither the quantitative value nor the rate of increase in Dengue NS1 antigen can be determined by this qualitative test.

**PERFORMANCE CHARACTERISTICS**

The ACCUCARE® ONE STEP DENGUE NS1 RAPID TEST has been evaluated with positive and negative samples confirmed by ELISA examination.

1) Dengue NS1 test :










Specimen	Accucare® One Step Dengue Duo		
	Positive	Negative	Total
Positive	99	1	100
Negative	4	296	300
Total	103	297	400

Sensitivity : 99.00 %      Specificity : 98.00 %

**BIBLIOGRAPHY**

1. CDC/NIH Guidelines. Biosafety in Microbiological and Biomedical Laboratories. 2nd Edition, 1988.
2. Lam, SK. Dengue haemorrhagic fever. Rev. Med. Micro. (1995), 6:39-48.
3. Siti-Strong. Diagnosis, prevention, and treatment of tropical disease, 7th ed., Philadelphia, the Ablakiston Company.

**GLOSSARY OF SYMBOL**

	Consult Instruction for Use	<b>LOT</b>	Lot Number
<b>REF</b>	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer		Do not reuse
<b>IVD</b>	For <i>in vitro</i> Diagnostic use only		Keep Dry
	Tests per Kit		Do Not Use if Damaged