Dengue NS1 Antigen Rapid Test Cassette (Colloidal Gold)

Cassette

Instruction for use

A lateral flow immunochromatographic assay for the rapid qualitative detection of dengue virus NS1 antigen in human whole blood, serum or plasma.

CE IVD REF

In Vitro Diagnosis
For Professional Use

PROUDCT SPECIFICATION
1T/BOX,10T/BOX,20T/BOX,25T/BOX，40T/BOX,50T/BOX

INTENDED USE
The Dengue NS1 Antigen Rapid Test Cassette (Colloidal Gold) is a lateral flow chromatographic immunoassay for the qualitative detection of dengue virus antigen (Dengue Ag) in human whole blood, serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with Dengue viruses. Any reactive specimen with the Dengue NS1 Antigen Rapid Test Cassette (Colloidal Gold) must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY
Dengue fever is an acute febrile arbo-viral disease affecting the tropical and subtropical regions of the world. The incidence of this disease has increased over the last 50 years with 2.5 billion people living in areas where dengue is endemic. It affects up to 100 million people each year, with 500,000 cases of dengue hemorrhagic fever (DHF) and dengue shock syndrome (DSS) and around 30,000 deaths, mostly amongst children. [1]
In view of the high mortality rate and to reduce the disease burden, it is imperative to have a rapid and sensitive laboratory assay for early detection of the disease. The major diagnostic methods currently available are viral culture, viral RNA detection by reverse transcriptase PCR (RT-PCR) and serological tests such as an immunoglobulin M(IgM) capture enzyme-linked immunosorbent assay (MAC-ELISA). However, early dengue diagnosis still remains a problem, as all these assays have their own pitfalls. The first two assays have restricted scope as a routine diagnostic procedure. Viral isolation by cell culture and subsequent detection by immunofluorescence, though the gold standard, [2] cannot be used as a routine diagnostic procedure due to its low sensitivity, laborious procedure and time consumption. The requirement of a highly trained staff, the need of asophisticated equipment as well as the cost factor associated with molecular methods has limited its application as a routine diagnostic assay. The MAC-ELISA, which is a commonly used assay, has a low sensitivity in the first four days of illness. [3]The requirement of paired sera at acute and convalescent phase, which improves the accuracy of the diagnosis, further delays it.
NS1 (non-structural protein) is a highly conserved glycoprotein that is essential for the viability of dengue virus (DV) and is produced both in membrane-associated and secretory forms by the virus. Enzyme-linked immunosorbent assays (ELISA) directed against NS1 antigen (NS1 Ag) have demonstrated its presence at high concentrations in the sera of dengue virus (DV) infected patients during the early clinical phase of the disease. [3] The Dengue NS1 Ag Rapid Test Cassette detects secretory NS1 protein and represents a new approach to the diagnosis of acute dengue virus (DV) infection.

TEST PRINCIPLE
The Dengue NS1 Ag Rapid Test Cassette is a lateral flow immunochromatographic assay. The test cassette consists of: 1) a red colored conjugate pad containing Mouse monoclonal anti-dengue NS1 conjugated with Colloid gold; 2) a nitrocellulose membrane strip containing a Test band (“T”) and a Control band (“C”). The T band is pre-coated with Mouse monoclonal anti-dengue NS1, and the C band is pre-coated with goat anti mouse IgG.
When the specimen is added into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. NS1 if present in the specimen will bind to the anti-dengue NS1 Ag -colloid gold. The immunocomplex is then captured by the reagent coated on the Test band (“T”), forming a red colored T band, indicating a dengue NS1 positive result and a recent dengue infection. Absence of the T band indicates a negative result. The Control band (“C”) is used for the procedural control, which should always appear if the test procedure is performed properly and the test reagents of control line are working.

MATERIAL PROVIDED
Test devices. Each test cassette is packed in a foil pouch with a package of desiccant.
Droppers
Assay buffer
Instruction for use

MATERIALS REQUIRED BUT NOT PROVIDED
1. Clock or Timer
2. A dry and clean specimen container
3. Centrifuge (for plasma only)
4. Micropipette
5. Lancets (for fingerstick whole blood only)

PRECAUTIONS
1. For professional and IN VITRO diagnostic use only.
2. The test should remain in the sealed pouch until use.
3. Do not use the kit if the foil pouch is punctured or not well sealed.
4. Do not reuse or use kits after the expiration date.
5. Do not mix components from kits with different lot number.
6. Avoid microbial contamination of reagents.
7. Wear gloves during the whole process and avoid reagents or specimen spilling-out. Wash hands thoroughly afterwards.
8. Dispose the used kit after decontamination of all liquids or solid wastes by following the local law or laboratory rule.
9. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
10. Dispose of all specimens and materials used to perform the test as biohazardous waste.
11. Handle the Negative and Positive Control in the same manner as patient specimens.
12. The testing results should be read within 20 minutes after a specimen is applied to the sample well or sample pad of the device. Read result after 25 minutes may give erroneous results.
13. Do not perform the test in a room with strong air flow, ie. electric fan or strong air-conditioning.

STORAGE AND STABILITY
Store the kit in cool and dry places at a temperature between 2-30°C. **Do not freeze.** The shelf-life of the kit under these storage conditions is 24 months.

SPECIMEN COLLECTION AND PREPARATION
The Dengue Ns1 Ag Rapid Test can be performed using **whole blood, serum or plasma.**
Drops of whole blood can be obtained by either finger tip puncture or veinpuncture. Do not use any hemolized blood for testing.

To collect Fingerstick Whole Blood specimens using a lancet:
1) Wash the patient’s hand with soap and warm water or clean with an alcohol swab. Allow to dry.
2) Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
3) Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
4) Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
Fingerstick Whole Blood specimens should be used immediately.

Collection by venipuncture
1) Collect whole blood into a collection tube (containing EDTA, citrate or heparin) by venipuncture.
2) If specimens are not immediately tested, they should be refrigerated at 2~ 8°C.For storage periods greater than three days, freezing is recommended. They should be brought to room temperature prior to use. Using the specimen after long-term storage of more than three days can cause non-specific reaction.
3) When stored at 2~8°C,the whole blood sample should be used within three days.

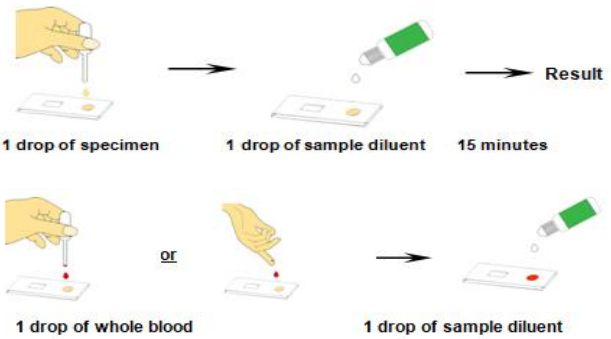
Collect serum or plasma specimens
1) Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
2) Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for 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.
3) 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.
4) If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

ASSAY PROCEDURES
Test device, patient’s samples, and controls should be brought to room temperature (10-30℃) prior to testing. Do not open pouches until ready to perform the assay.
1. Remove the test device from the foil pouch and place it on a clean and flat surface. Be sure to label the device with specimen’s ID number.
2. For whole blood test
   - Apply 1 drop of whole blood (about 30-40 μL) into the sample well.
   - Then add 1 drop (about 35-50 μL) of Sample Diluent immediately.
   For serum or plasma test
   - Fill the pipette dropper with the specimen.
   - Holding the dropper vertically, dispense 1 drop (about 30-40 μL) of

specimen into the sample well making sure that there are no air bubbles.
- Then add 1 drop (about 35-50 μL) of Sample Diluent immediately

3. Results can be read in 15 minutes. **Don't read result after 20 minutes. To avoid confusion, discard the test device after interpreting the result.**

Note: If migration (the wetting of membrane) is not observed in the test window after one minute, add one more drop of buffer to the specimen well.



INTERPRETATION OF ASSAY RESULT

(Please refer to the illustration)

Negative Result

Only one red control band (C) appears, and no test band (T).

Positive Result

In addition to a red colored control band (C), a distinct red colored I test band (T) will also appear.

The intensity of the test band ("T") may be less than that of the control band ("C"); this still means positive result.

Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.

Invalid Result

If no C band is developed, the assay is invalid regardless of color development on the T band as indicated below. Repeat the assay with a new device. If the problem persists, contact your local distributor.

QUALITY CONTROL

Dengue NS1 Ag Rapid Test Cassette has Test line T and Control line C on the surface of the membrane strip. Both the Test Line T and Control line C in the result window are not visible before applying sample, The Control Line C is used for the procedural control, which should appear if the test procedure is performed properly and the device is working properly.

LIMITATIONS

1. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
2. The Dengue NS1 Ag Rapid Test Cassette is limited to the qualitative detection of Dengue virus NS1 antigen in human whole blood, serum or plasma.
3. A negative result can occur if the quantity of Dengue virus NS1antigen present in the specimen is below the detection limits of the assay, or the antigens that are detected are not present during the stage of disease in which a sample is collected.
4. A negative test result cannot exclude a recent Dengue infection.

PERFORMANCE

The Dengue NS1 Ag Rapid Test Cassette has been evaluated with a leading commercial Dengue NS1 Ag EIA test. The results show that the overall relative sensitivity for Dengue NS1 Ag Rapid Test Cassette is 95.7% (66/69), and the relative specificity is 98.3% (226/230) and the relative accuracy is 97.7% (292/299).

Dengue NS1 Antigen Rapid Test vs. EIA

Method		Dengue NS1 EIA		Total results
Dengue NS1 Antigen Rapid Test	Results	Positive	Negative	
	Positive	66	4	70
	Negative	3	226	229
Total results		69	230	299

1. Interference

No interference was observed in the interference study of Dengue NS1 Ag Rapid Test tested with laboratory strains of common infectious diseases.

2. Accuracy

All results of each 10 of three batches of Dengue NS1 Ag Rapid Test Cassette were positive with high color uniformity when tested with Accuracy References.

BIBLIOGRAPHY

1. Chakravarti A, Kumaria R, Batra VV, Verma V. Improved detection of dengue virus serotypes from serum samples - Evaluation of single-tube multiplex RT-PCR with cell culture. Dengue Bulletin 2006;30:133-40.
2. Shu PY, Huang JH. Current advances in dengue diagnosis. Clinical and Diagnostic Laboratory Immunology 2004;11:642-50.

Dussart P, Labeau B, Lagathu G, Louis P, Nunes MRT, Rodrigues SG, *et al.* Evaluation of an Enzyme Immunoassay for detection of dengue virus NS1 antigen I human serum. Clin Vaccine Immunol 2006;13:1185-9.

Code:GKPD035-1 Effective date: May 27, 2024

Index of Symbols

IVD	For in vitro diagnostic use only		Do not reuse
	Expiry date		See instruction for use
	Warning, please refer to the instructions in the annex		Manufacturer
2℃ 30℃	Temperature scope within which the product is reserved	LOT	Batch number
REF	Catalog #	Σ	Tests / box
EU REP	European union authorized representative		Keep dry
	Keep away from sunlight		Don't use the product when the package is damaged
	Biological risks		
CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		

Manufacturer:
Dezhou Guoke Medical Technology Co., Ltd
Add.: 28-31 axis,1 and 2 span, No.2 workshop, (Zhongyuan Science and Technology Innovation Park) No. 6596 Dongfanghong East Road, Yuanqiao Town, Economic and Technological Development Zone, Dezhou City, Shandong Province,China
E-mail: office@guoke-medical.com

European Authorized Representative:
Riomavix S.L.
Add.: Calle de Almansa 55,1D, Madrid 28039 Spain
E-mail: riomavix@gmail.com