Dengue IgG/IgM Antibody Rapid Test Cassette (Colloidal Gold)

Cassette

Instruction for use

A lateral flow immunochromatographic assay for the rapid qualitative detection and differentiation of NS1 IgG and IgM antibodies to dengue virus in human whole blood, serum or plasma

CE IVD REF

In Vitro Diagnosis
For Professional Use

PACKAGING SPECIFICATION
1T/box,10T/box,20T/box,25T/box,40T/box,50T/box

INTENDED USE
The Dengue IgG/IgM Antibody Rapid Test Cassette (Colloidal Gold) is a lateral flow immunochromatographic assay for the rapid qualitative detection and differentiation of IgG and IgM antibodies to dengue virus in human whole blood, serum or plasma. It is intended for professional use to aid in the presumptive diagnosis for primary and secondary dengue infection. This test provides only a preliminary test result. Therefore, isolation of virus, antigen detection in fixed tissues, RT-PCR and serological test like haemagglutination-inhibition test, more specific alternative diagnosis method must be used in order to obtain a confirmation of dengue virus infection.

SUMMARY
Dengue viruses, transmitted by the mosquito, Aedes aegypti and Aedes albopictus mosquitoes, are widely distributed throughout the tropical and subtropical areas of the world. There are four known distinct serotypes (dengue virus 1,2,3 and 4). In children, infection is often subclinical or causes a self-limited febrile disease. However, if the patient is infected second times with a different serotype, a more severe disease, dengue hemorrhagic fever or dengue shock syndrome, is more likely to occur. Dengue is considered to be the most important arthropod-borne viral disease due to the human morbidity and mortality it causes.
Traditionally, the serological diagnosis of an acute dengue virus infection has relied on showing a 4-fold or greater rise in anti-dengue virus antibody between paired acute- and convalescent-phase sera from a patient. The haemagglutination-inhibition test has been the most commonly used serological assay for dengue diagnosis.
Rapid and reliable tests for primary and secondary infections of dengue are essential for patient management. Primary Dengue infection is associated with mild to high fever, headache, muscle pain and skin rash. Immune response includes IgM antibodies produced by 5th day of symptoms and persist for 30—60 days. IgGs appear the 14th day and persist for life. Secondary infections often result in high fever and in many cases with haemorrhagic events and circulatory failure. Secondary infections show that IgGs rise within 1-2 days after the onset of symptoms and induce IgM response after 20 days of infection.

PRINCIPLE
The Dengue IgG/IgM Antibody Rapid Test Cassette (Colloidal Gold) is designed to simultaneously detect and differentiate IgG and IgM antibodies to dengue virus in human serum, plasma or whole blood. This test can also detect all 4 dengue serotypes by using a mixture of recombinant dengue envelope proteins.
Dengue IgG/IgM test device has 3 pre-coated lines, “T1” (Dengue IgM Test Line), “T2” (Dengue IgG Test Line) and “C” (Control Line) on the surface of the membrane. All three lines in result window are not visible before applying any samples. The “Control Line” is used for procedural control. The control line should always appear if the test procedure is performed properly and the test reagents of the control line are working. Pink “T1” and “T2” lines will be visible in the result window if there are enough IgM and/or IgG antibodies to dengue virus in the sample. If IgM and/or IgG antibodies to dengue virus are not present in the sample, there will be no color appearance in “T1” and/or “T2”.
When a specimen is added to the sample well, anti-dengue IgGs and IgMs in the specimen will react with recombinant dengue virus envelope proteins-colloidal gold conjugates and form a complex of antibodies-antigen. As this complex migrates along the length of the test device by capillary action, it will be captured by the relevant anti-human IgG and/or anti-human IgM immobilized in two test lines across the test device and generate a colored line.

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

MATERIALS REQUIRED BUT NOT PROVIDED
Clock or Timer A dry and clean specimen container
Centrifuge (for plasma only) Micropipette
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. The testing results should be read at 15-20 minutes after a specimen is applied to the sample well or sample pad of the device. Read result after 20 minutes may give erroneous results.

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.

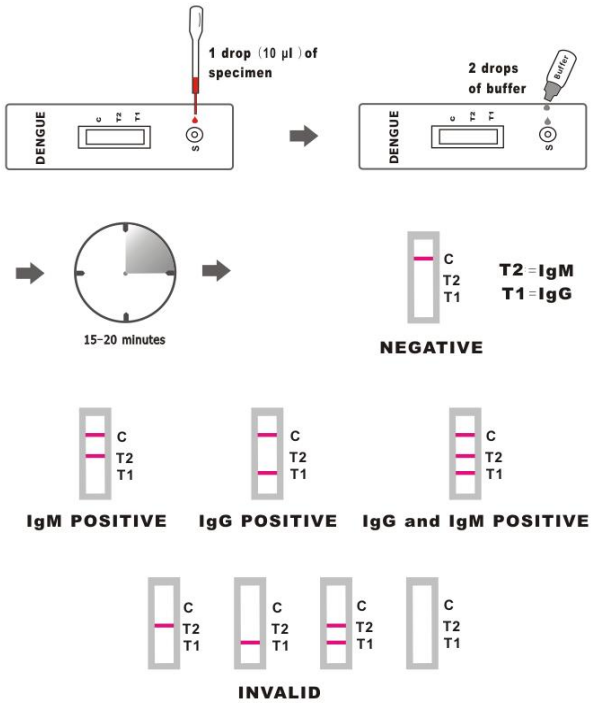
SPECIMEN COLLECTION AND PREPARATION
The DengueIgG/IgM Rapid Test can be performed using **whole blood, serum or plasma.**
Drops of whole blood can be obtained by either finger tip puncture or veinpuncture. Do not use any hemolized blood for testing.
To collect Fingerstick Whole Blood specimens using 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.

If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

ASSAY PROCEDURE
Test device, patient’s samples, and controls should be brought to room temperature (15-30℃) 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. Use the provided dropper or a micropipette to add 1drop (10ul) of serum, plasma or whole blood specimen into the sample well (S). Then add 2 drops of assay buffer (about 80ul) to the sample well. And start the timer.
3. Interpret test results at 15-20 minutes. Don’t read result after 20 minutes.



INTERPRETATION OF RESULTS
(Please refer to the illustration)

NEGATIVE
Only the Control line (C) is visible. No T2 line or T1 line appears. The result is negative.

POSITIVE
IgM Positive
The Control line (C) and a colored T2 line (IgM) appear. This is positive for IgM antibodies to Dengue virus and is indicative of a primary dengue infection.
IgG Positive
The Control line (C) and a colored T1 line (IgG) appear. This is positive for IgG antibodies to Dengue virus and is indicative of secondary or past dengue infection.
IgG and IgM Positive
The Control line and both colored T2 test line (IgM) and T1 test line (IgG) appear. The color intensities of the lines do not have to match. This is positive for both IgM and IgG antibodies and is indicative of a secondary dengue infection.
Note: The intensity of the color in the TEST line regions (T1 and T2) may vary depending on the concentration of Dengue antibodies present in the specimen. Therefore, any shade of color of the TEST lines (IT1 and/or T2) should be considered positive.
Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.
INVALID
Result is invalid if Control line (C) is not colored, regardless of any colored line in the T2 line (IgM) or T1 line (IgG). Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test device. If the problem persists, discontinue using the kit immediately and contact your local distributor.

LIMITATION OF TEST
1. As the result of all qualitative diagnostic tests, all results of this test must be interpreted together with other clinical information or diagnosis methods available to the physician.
2. If the test result is negative and clinical symptoms persist, additional follow-up test using other clinical methods is recommended. A negative result does not preclude the possibility of an early infection of Dengue
3. In early infections and some secondary infections, detectable levels of IgM antibodies may be low. Some patients may not produce detectable levels of antibody within the first seven to ten days after infection. If symptoms persist, the test should be repeated after 3~10 days with the first specimen of patient.
4. Serological cross-reactivity with the Flavivirus group (Dengue virus, St. Louis encephalitis, Japanese encephalitis, West Nile and yellow fever virus) is common.

EXPECTED VALUE
Dengue IgG/IgM Rapid Test vs. ELISA

Dengue Infection	Result	Ig M	IgG
Primary Infection	Positive	14	0
	Negative	3	17
	Total	17	17
	Relative Sensitivity	**82.4%**	**0%**
Secondary Infection	Positive	39	55
	Negative	16	0
	Total	55	55
	Relative Sensitivity	**70.9%**	**>99.0%**
Non-Dengue Infection	Positive	0	0
	Negative	378	378
	Total	378	378
	Relative Specificity	**>99.0%**	**>99.0%**

Primary dengue is characterized by the presence of detectable IgM 3-5 days after the onset of infection. Secondary dengue is characterized by the elevation of specific IgG 1-2 days after the onset of infection and in the majority of cases this is generally accompanied by an elevation of IgM.

PERFORMANCE
The Dengue IgG/IgM Antibody Rapid Test Cassette (Colloidal Gold) has been evaluated with specimens obtained from symptomatic and asymptomatic individuals. Results were confirmed by a leading commercial Dengue ELISA test. The results show that the overall relative sensitivity for the primary and secondary infection of the Dengue IgG/IgM Antibody Rapid Test (Colloidal Gold Method) is 95.8%, and the relative specificity is >99.0%, and the relative accuracy is 99.3%.

Precision
Intra-Assay
Within-run precision has been determined by testing 15 replicates of four specimens: a negative, an IgG positive, an IgM positive and an IgG/IgM dual positive. The specimens were correctly identified >99.9% of the time.

Inter-Assay
Between-run precision has been determined by testing 15 independent assays on the same four specimens: a negative, an IgG positive, an IgM positive and an IgG/IgM dual positive. Three different lots of the Dengue IgG/IgM Antibody Rapid Test (Colloidal Gold Method) have been tested using these specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity
The Dengue IgG/IgM Antibody Rapid Test Cassette (Colloidal Gold) has been tested by HAMA, RF, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb Syphilis, HIV, HCV, H.Pylori, MONO, CMV, Rubella and TOXO positive specimens. The results showed no cross-reactivity.

BIBLIOGRAPHY
1) Dengue haemorrhaic fever: Diagnosis, treatment, prevention and control. WHO 2nd Edition 1997
2) Songee L. ranch and Paul N. Levett. Evaluation of four methods for detection of immunogloulin M antibodies to dengue virus. Clin. Diagn. Lab. Immunol. Vol 6(4) p 555-557,1999
3) Jan Groen et al. Evaluation of six immunoassays for detection of dengue-virus specific immunoglobulin M and G Antibodies. Clin. Diagn. Lab. Immunol. Vol 7(6) p 867-871,2000

Code:GKPD036-1 Effective date: May 28, 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		

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