Dengue NS1/IgG/IgM Rapid Test Kit
(Immunochromatographic Assay)
User Instruction

Intended Use

The Dengue NS1/IgG/IgM Rapid Test Kit (Immunochromatographic Assay) is an immunochromatographic assay for the qualitative detection of NS1 Ag and the differential detection of immunoglobulin G (IgG) and immunoglobulin M (IgM) against all types of dengue viruses using human serum, plasma, or whole blood.

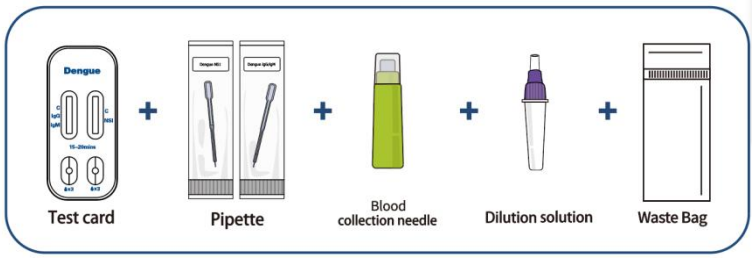
Test Principle

In the Dengue NS1 Antigen Strip, the dengue virus-specific antibody is placed in a conjugate pad in complex with a gold conjugate, and the anti-dengue NS1 antibody is immobilized on the membrane. When a dengue antigen positive sample is loaded into the sample well, the immobilized anti-dengue NS1 antibody captures the antigen. The antigen then reacts with the dengue-specific antibody-gold complex to form a visible band on the detection line. The solution continues to migrate and encounters a control line antibody bound to a control conjugate, resulting in a second red line.

In the Dengue IgG/IgM test strip, the antigen-gold conjugate complex is placed in a binding pad and the anti-human IgG and anti-human IgM are coated on the membrane. The antibodies are captured by the membrane when a Dengue antibody-positive sample is loaded into the sample wells. In the wells, immobilized anti-human antibodies then capture these antibodies. The antibodies then react with the dengue-specific antigen-gold complex to form a visible band in the region of the detection line. The solution continues to migrate and encounters the control line antibody bound to the control conjugate, resulting in a second red line.

The kit detects antigens and antibodies to all serotypes of dengue virus.

Materials Provided



Storage

The original package shall be stored in a dry place away from light at 2 - 30 ℃, the shelf life is 2 years and shall not be frozen. The reagent shall be used as soon as possible within 1 hour after the unpacking of the aluminum foil bag; it is recommended to use the reagent as soon as possible when the ambient temperature is higher than 30°C or high humidity.

Limitations of The Test

1. The test results of this kit are only for the reference of clinicians and should not be used as the sole basis for clinical diagnosis and treatment. Clinical management of patients should be considered in the context of their symptoms/signs, medical history, other laboratory tests and response to treatment.
2. A negative result for an individual subject indicates absence of detectable antigen. However, it does not preclude the possibility of exposure to or infection with plasmodium.
3. A negative result can occur if the quantity of the antigen present in the specimen is below the

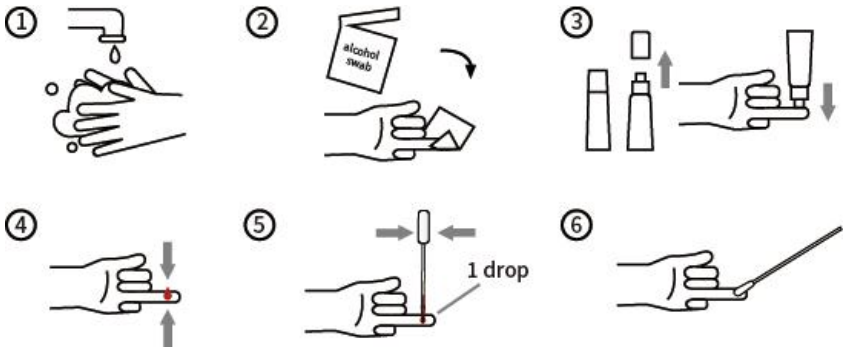
detection limits of the assay, or the antigen that are detected are not present during the stage of disease in which a sample is collected.

4. Some specimens containing unusually high concentration of heterophile antibodies or rheumatoid factor may affect expected results.

Specimen Requirements

Fingertip blood:

1. Wash hands with soap and warm water, open the disposable fingertip blood collection kit .
2. Clean the abdomen of the finger to be tested with an alcohol swab. Allow to dry.
3. Puncture the finger with a disposable fingertip blood sampler. The ring finger takes priority, followed by the middle finger. Infants and young children can use their heels.
4. Wipe away the first sign of blood. Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
5. Use a disposable dropper to draw sample to specimen line.
6. Apply cotton swab pressure to stop the bleeding.



Venous Blood:

Collect whole blood in a clean container containing anti-coagulant (EDTA, citrate or heparin) by venipuncture. Blood can be obtained by finger tip puncture as well.Whole blood specimen should be stored in refrigeration (2°C-8°C) if not tested immediately for up to 3 days.

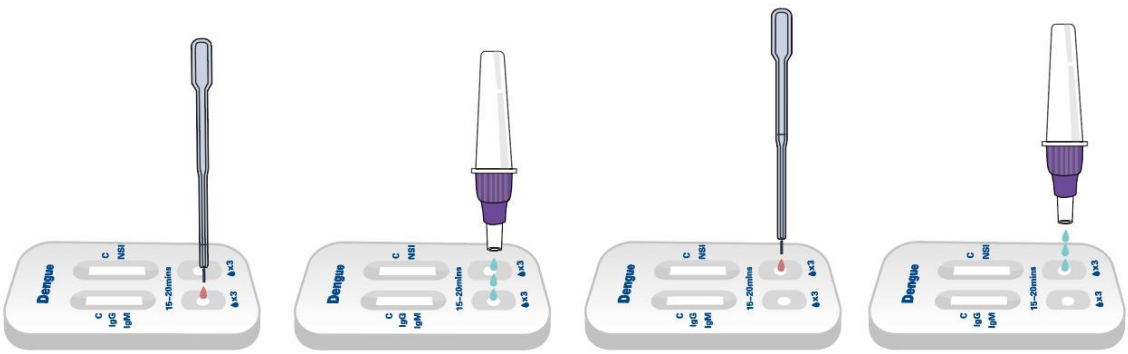
Test Method

Step 1: Before testing, carefully read the product manual and restore the strip and sample to room temperature before use.

Step 2: Open the pouch and place the test card on a clean and flat surface.

Step 3: Drop 1 drop of sample (approximately 5 μ L) vertically into the IgG/IgM detection well of the kit using ‘Dengue IgG/IgM’ dropper, and then drop 3 drops of dilution solution.

Step 4: Drop 1 drop of sample (approximately 25 μ L) vertically into the NS1 detection well of the kit using ‘Dengue NS1’ dropper, and then drop 3 drops of dilution solution.



Step 5 Read results in 15-20 minutes. Don’t read results after 30 minutes.

Interpretation of Test Results

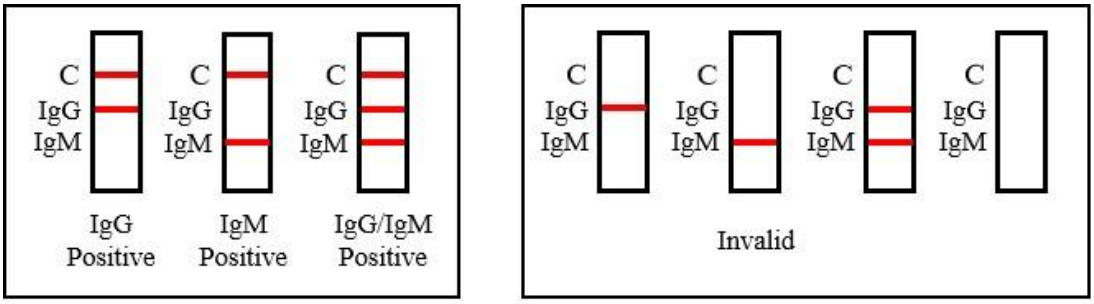
Test Results of dengue IgG/IgM :

IgG Positive: Two red lines, both C and IgG lines appear. Indicates secondary infection with dengue virus or previous infection with dengue virus.

IgM Positive: Two red lines, both C and IgM lines appear. Indicates first-time infection with dengue virus.

IgG/IgM Positive: Three red lines appear. C, IgG and IgM lines all appear. Indicates the late stage of initial infection or early stage of secondary infection.

Invalid: If no C band is developed, the assay is invalid regardless of any burgundy color in the test bands as indicated below. Repeat the assay with a new device.

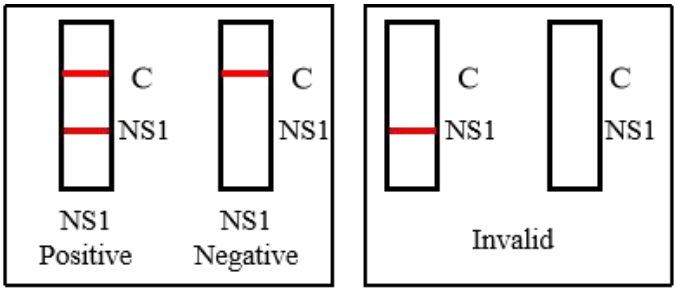


Test Results of dengue NS1 :

NS1 Positive: Two lines, both C and IgG lines appears.

NS1 Negative: One line, only C line appears.

Invalid: If no C band is developed, the assay is invalid regardless of any burgundy color in the test bands as indicated below. Repeat the assay with a new device.



Preformance Characteristics

1. The width of the membrane strip of this kit is not less than 3.0 mm, and the liquid migration speed is not less than 10 mm/min.

2. Negative/positive reference coincidence rate.

All the positive references are positive for the corresponding plasmodium, which is consistent with the known results of the reference; all the negative references are negative for the orresponding plasmodium.

3. Repeatability

Repeated testing was conducted for repeatable reference products for 10 times. The test results were consistent with the known results of the reference products and were uniform in color.

4. Analytical specificity

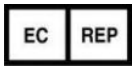
The kit does not cross react with measles, rubella, influenza A, typhoid, leptospirosis, hemorrhagic fever with renal syndrome, sepsis, epidemic cerebrospinal meningitis, hepatitis B virus, hepatitis C virus, AIDS, and scrub typhus positive samples.

Precautions

1. This is a single-use in vitro diagnostic reagent, do not reuse, and do not use expired products.
2. All test specimens must be considered potentially infectious, and during collection, processing, storage, mixing of specimens and testing should be taken appropriate protective measures. Therefore, wear protective measures such as wearing gloves and masks should be done, and dispose of all wastes as potentially biohazardous items. (Used cotton swabs, test cards, extraction tubes, etc., should be decontaminated before disposal and tested for autoclaving.)
3. Do not mix use different batches of test cards and sample diluent.
4. Operate at room temperature. Test cards kept at low temperature should be restored to room temperature before opening to avoid moisture absorption.
5. Do not use reagent kits with obvious damage or test cards with damaged or expired packaging.
6. The aluminum foil pouch contains desiccant and must not be taken orally.
7. Ensure proper sample loading volume, results of too much or too little sample loading volume may not be credible.
8. If the initial screen is a positive sample, contact your local public health agency.
9. As with the diagnostic reagents used, the final diagnosis should be made by a physician after combining the various test parameters and clinical symptoms.
10. If you have any questions or suggestions on the use of this kit, please contact the manufacturer.
11. For unknown reasons, long-term use of some drugs may lead to false positive results of the test, which are not covered by the interfering substances.

Symbols

					
Date of manufacture	Keep away from sunlight	Keep dry	Do not re-use	Manufacturer	Batch code
					
Do not use if package is damaged	For *In Vitro* Diagnostic Use	Consult instructions for use	Temperature limit	Expiration date	CE mark of conformity

	BioTeke Corporation (Wuxi) Co., Ltd. No. 90, Huiming Road, Huishan, Wuxi City, Jiangsu,214000, China
	MedUnion S.L. Carrer de Tapioles, 33, 2-1, 08004, Barcelona, Spain
	Revision date: March 24, 2025 Edition: A0