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Dengue NS1 Ag
Fast Test Kit
(Immunofluorescence Assay)

IF1136 for Getein 1100
IF5136 for Getein 1160
REF **IF3136 for Getein 1180**
IF4136 for Getein 1200
IF2136 for Getein 1600

User Manual

INTENDED USE

Dengue NS1 Ag Fast Test Kit (Immunofluorescence Assay) is intended for qualitative detection of dengue NS1 antigen in human serum, plasma or whole blood. It is used as an aid in the early clinical assessment of Dengue virus infection.

SUMMARY

Dengue fever is caused by dengue virus (divided into 4 serotypes, DENV-1-4). It is an acute infectious disease transmitted by Yi ant Aegypti and Aedes albopictus. It is most common in tropical and subtropical areas. Clinical types can be divided into three types: dengue fever, dengue hemorrhagic fever and dengue shock syndrome. The disease spreads rapidly, and the main clinical manifestations include fever, headache, generalized muscle and joint pain, extreme fatigue, rash, lymphadenopathy, and leukopenia. Primary dengue virus infection patients, general clinical manifestations is lighter, can show the asymptomatic recessive infection, or light, typical dengue: alien dengue virus infection again, serious illness, dengue hemorrhagic fever and shock syndrome in clinical probability increases, case fatality rate is high, is a serious harmfulness of infectious diseases.

PRINCIPLE

Dengue NS1 Ag Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay based on the double antibody sandwich principle. After the sample has been applied to the test strip, the fluorescence latex-labelled dengue NS1 monoclonal antibody binds with the dengue NS1 antigen in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by another dengue NS1 monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of dengue NS1 antigen in sample. Fluorescent signals intensity can be analyzed by applicable device thus the dengue NS1 antigen in sample can be detected qualitatively.

CONTENTS

1. A kit for Getein 1100/Getein 1160/Getein 1180 contains:
Package specifications: 25 tests/kit, 10 tests/kit
1) Dengue NS1 Ag test card
2) Disposable pipet
3) Sample diluent
4) User manual: 1 piece/kit
5) SD card: 1 piece/kit
2.A kit for Getein 1200/Getein 1600 contains:
Package specifications: 2×24 tests/kit, 2×48 tests/kit
Sealed cartridge with 24/48 Getein Dengue NS1 Ag test cards
User manual: 1 piece/kit
Materials required for Getein 1200/Getein 1600:
1) Sample diluent: 1 bottle/kit
2) Box with pipette tips: 96 tips/kit
3) Mixing plate: 1 piece/kit"
3. Sample diluent composition:
Phosphate buffered saline, preservative.
4. A test card consists of:
A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane, absorbent paper and liner. The test card contains fluorescence latex-labelled dengue NS1 monoclonal antibody, dengue NS1 monoclonal antibody and goat anti-mouse IgG antibody.
Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer
Getein 1200 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test kit at 4~30°C with a valid period of 24 months. Use the test card for Getein 1100/Getein 1160/Getein 1180 within 1 hour once the foil pouch is opened. For test card of Getein1200/Getein1600: If the cartridge is opened, it could be stable within 24 hours once exposure to air. Please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Do not use the kit beyond the expiration date.
3. Do not use the test card if the foil pouch is damaged.
4. Do not open pouches until ready to perform the test.
5. Do not reuse the test card.
6. Do not reuse the sample diluent.
7. Handle all samples as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
8. Carefully read and follow user manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum, plasma and whole blood*** samples. ***Sodium citrate, heparin and EDTA*** can be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis. Lipemic samples must be excluded from testing.
2. The test should be performed within 4 hours after blood collection.
3. If testing is delayed, serum and plasma sample may be stored up to 3 days at 2~8°C or stored at -20°C for 1 month before testing (whole blood sample may be stored up to 3 days at 2~8°C).
4. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
5. Do not use heat-inactivated or hemolysis samples.
6. SAMPLE VOLUME(for Getein 1100/Getein 1160/Getein 1180) : ***100 μL***.

TEST PROCEDURE

1. Before use, you must carefully read the instructions for use and operate in strict accordance with the instructions for use, otherwise reliable results cannot be guaranteed.

2. Test card, sample and reagent should be brought to room temperature before testing.
3. Select the corresponding mode on the analyzer according to the sample type (see the instructions for use of analyzer for details).

For Getein 1100:

1. Confirm SD card lot No. in accordance with test kit lot No.. Read the relevant information in the SD card for calibration.
2. Remove the test card from the sealed pouch before use. Label the test card with patient identification.
3. Put the test card on a clean table, horizontally placed.
4. Using disposable pipet, deliver ***100 μL*** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop ***100 μL*** of sample mixture into the sample well on the test card.
5. ***Reaction time: 15 minutes***. Insert the test card into Getein1100 and press "ENT" button or click on "Start" icon (for Android Getein 1100) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

1. Confirm SD card lot No. in accordance with test kit lot No. Perform "SD card" calibration when necessary.
2. Enter testing interface of Getein 1160/Getein 1180.
3. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
4. Put the test card on a clean table, horizontally placed.
5. Using sample transfer pipette, deliver ***100 μL*** of sample into one tube of sample diluent and mix thoroughly. Then drop ***100 μL*** of sample mixture into sample well on the test card.
6. Insert the test card into Getein 1160/Getein 1180 immediately after sample loading. The analyzer will count down the reaction time (15 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1200/Getein 1600:

1. Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card which can calibrate automatically.
2. Put the sample diluent at the correct position in Getein 1200/ Getein 1600.
3. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein 1200/ Getein 1600 will do the testing and print the result automatically.

Notes:

1. It is required to perform "SD card" calibration when using a new batch of kits.
2. It is suggested to calibrate once for one batch of kits for Getein 1100/Getein 1160/Getein 1180.
3. Make sure the test card and the sample insertion is correct and complete.

DISPLAY AND INTERPRETATION OF TEST RESULTS

Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein 1100/Getein 1160/Getein 1180/Getein 1200/ Getein 1600.

PERFORMANCE CHARACTERISTICS

1. Positive reference coincidence rate:
   10 Dengue NS1 Ag enterprise positive references are tested and the positive reference coincidence rate is 10/10.
2. Negative reference coincidence rate:
   10 Dengue NS1 Ag enterprise negative references are tested and the negative reference coincidence rate is 10/10.
3. Limit of detection: 4 Dengue NS1 Ag enterprise references of limit of detection (L1~L4) are tested, and the L1, L2 should be positive, the L3 could be positive or negative and the L4 should be negative.
4. Measuring Range 1.00-50.00 S/CO
5. Within-run Precision: ≤10%.
6. Between-run precision: ≤15%.

LIMITATIONS

1. As all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
2. A false-negative result could occur if the concentration of dengue NS1 antigen is below the lower limit of detection. In this case, further tests are required if signs of symptom persisted.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Dengue NS1 Ag Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult *instructions for use* or consult electronic *instructions for use*	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community/European Union
CE	CE mark		Do not use if package is damaged and consult *instructions for use*
REF	Catalogue number		

Thank you for purchasing Dengue NS1 Ag Fast Test Kit (Immunofluorescence Assay). Please read this package insert before operating to ensure proper use.

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