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CE IVD

Dengue NS1 Ag

Fast Test Kit

(Immunofluorescence Assay)

User Manual

REF IF1136

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 Getein1100 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 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

Getein1100 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 within 1 hour once the foil pouch is opened.

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. 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).
3. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
4. SAMPLE VOLUME：***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 Getein1100:

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 Getein1100) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

DISPLAY AND INTERPRETATION OF TEST RESULTS

1. Getein1100 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100.
2. Samples with concentration <1.00 S/CO are considered negative and indicate no dengue NS1 antigen was detected.
3. Samples with concentration ≥1.00 S/CO are considered positive and indicate the presence of dengue NS1 antigen.
4. Due to different methodologies or antibody specificity, there may be deviations between the test results of different manufacturers, so they can't be compared directly.

Note:

1. Positive results indicate the presence of dengue NS1 antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. A positive result does not rule out co-infections with other pathogens.
2. Negative test results cannot preclude infection and should not be used as the sole basis for treatment or other patient management decisions, including infection control decisions, particularly in the presence of clinical signs and symptoms consistent with dengue or in those who have been in contact with the virus. It is recommended that these results be confirmed by a molecular testing method, if necessary, for patient management.

PERFORMANCE CHARACTERISTICS

1. Measuring Range 1.00-50.00 S/CO
2. Within-run Precision ≤10%
3. 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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