GP CE IVD

Dengue IgG/IgM Antibody Fast Test Kit (Immunofluorescence Assay)

IF1137 for Getein 1100
IF2137 for Getein 1600
IF3137 for Getein 1180
IF4137 for Getein 1200
IF5137 for Getein 1160

Instructions for use REF

INTENDED USE

Dengue IgG/IgM Antibody Fast Test Kit (Immunofluorescence Assay) is intended for the qualitative detection of dengue IgG/IgM antibody in human serum, plasma or whole blood samples. The test is used as an aid for the diagnosis of dengue fever. For professional and laboratory use.

SUMMARY

Dengue virus has four serotypes, known as DENV-1, DENV-2, DENV-3, and DENV-4, which can cause dengue fever. It belongs to the genus Flavivirus within the family Flaviviridae. The dengue virus is primarily transmitted through the bites of infected mosquitoes, such as Aedes aegypti and Aedes albopictus. Dengue fever is an acute infectious disease that can range from mild flu-like symptoms to severe hemorrhagic fever and shock syndrome. After infection, the human body produces a specific immune response against the dengue virus, including the production of IgG and IgM antibodies.

During the early stages of dengue infection, the immune system first produces dengue IgM antibodies, which are part of the initial immune response and provide short-term protection. Over time, the level of dengue IgM antibodies decreases while the production of dengue IgG antibodies begins and gradually increases. Dengue IgG antibodies have a higher affinity and are more effective at neutralizing the virus. If dengue IgG/IgM antibodies are present in someone's blood sample, it typically means they have been infected with the virus at some point in the past and may have some degree of protection against reinfection.

PRINCIPLE

Dengue IgG/IgM Antibody Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunochromatographic assay for the detection of dengue IgG/IgM antibody in human serum, plasma and whole blood samples. After the sample has been applied to the test card, the fluorescence labelled recombinant dengue antigen binds with dengue IgG antibody or dengue IgM antibody in sample and forms corresponding marked antigen-antibody complex. The complex moves to the detection area by capillary action, then it is captured by anti-human IgG antibody or anti-human IgM antibody coated on the detection area of nitrocellulose membrane, forming the antigen-anti-body-anti-human IgG antibody complex or antigen-anti-body-anti-human IgM antibody complex. The fluorescence intensity of the test line increases in proportion to the amount of dengue IgG antibody and IgM antibody in the sample. Fluorescent signals intensity can be analyzed by applicable device thus the dengue IgG/IgM antibody in sample be detected.

APPLICABLE DEVICE

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

CONTENTS

Materials	Getein 1100/Getein 1160/ Getein 1180		Getein 1200/ Getein 1600	
	10 T/kit	25 T/kit	2*24 T/kit	2*48 T/kit
Test card*	10 pcs	25 pcs	24 test cards in 1 cartridge, and 2 cartridges in 1 box	48 test cards in 1 cartridge, and 2 cartridges in 1 box
Disposable pipet	10 pcs	25 pcs	/	/
Sample diluent**	10 tube	25 tube	1 box	1 box
Instructions for use	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	1 pc in each cartridge	1 pc in each cartridge

*Test card

A test card consists of: Fluorescence labelled recombinant dengue antigen, anti-human IgG antibody, anti-human IgM antibody and polyclonal IgG antibody.

**Sample diluent

(1) Sample diluent for Getein 1100/Getein 1160/Getein 1180 is each tube main consists of: phosphate buffer (20 mmol/L), NaN3 (＜0.1%).

(2) Sample diluent for Getein 1200/Getein 1600 is an independent packing box consists of:

Sample diluent main contains phosphate buffer (20 mmol/L), NaN3 (＜0.1%) (25 mL/bottle for Getein 1200, 30 mL/bottle for Getein 1600), box with pipette tips (96 tips/box) and mixing plate (1 piece/box).

Note:

1. The standard curve data can be written to RFID card in the kit. According to the function of RFID card, we define it as "Standard Curve Data Card", short for "SD Card".
2. Do not mix or interchange different batches of kits.

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 Getein 1200/Getein 1600: 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 or the cartridge is damaged.
4. Do not open pouches or the cartridge until ready to perform the test.
5. Do not reuse the test card or pipet.
6. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
7. Carefully read and follow instructions for use to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. Serum, plasma and whole blood can be used as samples in the assay.
2. Heparin, sodium citrate and EDTA can be used as the anticoagulants for plasma and whole blood. Do not use hemolytic specimens.
3. This assay is designed and validated for use with human blood, other specimens or body fluids may not get accurate results.
4. It is recommended to test the sample within 4 hours after collection. Serum and plasma are stable for 5 days when stored at 2~8°C and 6 months when stored at -20°C. Whole blood is stable for 3 days when stored at 2~8°C.
5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.

TEST PROCEDURE

1. User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
2. Test kit and sample should be brought to room temperature before testing.

For Getein 1100:

1. Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD card” calibration when necessary.
2. Select the corresponding “Sample” on the analyzer according to the sample type (see the user manual of analyzer for details).
3. Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
4. Use disposable pipet or pipette, deliver 100 μL of sample into one tube of sample diluent, mix 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 Getein 1100 and click on “Start” icon 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. Select the corresponding “Sample” on the analyzer according to the sample type (see the instructions of analyzer for details).
3. Remove the test card from the sealed pouch immediately

before use and put the test card on a clean table, horizontally placed.

4. Use disposable pipet or pipette, deliver 100 μL of sample into one tube of sample diluent, mix thoroughly. Then drop 100 μL of sample mixture into the sample well on the test card.
5. 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 displayed 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 insertion of test card and the sample are correct and complete.

LIMITATIONS

1. In order to achieve the purpose of diagnosis, this test result should be used in combination with clinical examination, medical history and other examination results.
2. Some substances in blood as listed below may interfere with the test and cause erroneous results. The maximum allowance concentration of each is as follows:

Interferent	Concentration (Max)
Triglyceride	18 g/L
Bilirubin	0.2 g/L

PERFORMANCE CHARACTERISTICS

Measuring Range 0.50-100.00 COI
Within-run Precision ≤ 10%
Between-lot Precision ≤ 15%

DISPLAY AND INTERPRETATION OF TEST RESULTS

1. Getein 1100/Getein 1160/Getein 1180/Getein 1600/Getein 1200 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 1600/Getein 1200.
2. The test result is displayed numerically in terms of cut-off index (COI) value. Test result is negative if COI is <1.00 and positive if COI is ≥1.00.

Item	Display	Judgenment
Dengue IgM	COI ≥ 1.00	Positive test for dengue IgM antibody (Dengue IgM antibody present)
	COI < 1.00	Presumptive negative test for dengue IgM antibody (no dengue IgM antibody detected)
Dengue IgG	COI ≥ 1.00	Positive test for dengue IgG antibody (Dengue IgG antibody present)
	COI < 1.00	Presumptive negative test for dengue IgG antibody (no dengue IgG antibody detected)
Invalid Test		Test invalid, repeat the test (some procedural error or malfunction of test cards and/or analyzers)

3. Cut-off index of dengue antibody has been determined and validated using 500 negative samples, 92 dengue IgG positive samples and 84 dengue IgM positive samples.
4. It is recommended that each laboratory establish its own expected values for the population it serves.

Note:

1. Due to the limitation of immunochromatography methodology, the negative test result does not exclude the infection of dengue. In the early stage of infection, the lack of IgG/IgM antibody production or very low concentration will lead to false negative results.
2. False positive results may occur due to cross-reacting antibodies from previous infections, or from other causes.
3. Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnostic determination is made.
4. The individual immune response following dengue infection varies considerably and might give different results with assays from different manufacturers. Results of assays from different manufacturers should not be used interchangeably.

REFERENCES

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DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Dengue IgG/IgM Antibody 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		Caution

Thank you for using Dengue IgG/IgM Antibody Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use.

Version: WIF92-S-01

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