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CE IVD

Total IgE

Fast Test Kit

(Immunofluorescence Assay)

IF1069 for Getein1100
IF5069 for Getein1160
IF3069 for Getein1180
IF4069 for Getein1200
IF2069 for Getein1600

REF

Instructions for Use

INTENDED USE

Total IgE Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of circulating total IgE antibodies in human serum, plasma and whole blood samples. This test can be used as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings.

SUMMARY

IgE is an immunoglobulin with a molecular weight of approximately 190,000 daltons. Produced by plasma cells, IgE has a significant role in atopic diseases such as allergic rhinitis, allergic asthma, and atopic dermatitis. IgE has a high affinity for receptors on mast cells and basophils, mediating the binding of allergens to these cells. The subsequent release of vasoactive amines, such as histamine, produce the clinical manifestations associated with atopic disease. Measurement of IgE serum levels can be important in the diagnosis and treatment of these disorders.

In most nonatopic patients, IgE serum levels are relatively low. However, certain parasitic or helminth infections have been associated with elevated IgE levels due to IgE sensitization of macrophages, eosinophils, and other inflammatory cells. The IgE concentration in a patient is dependent on both the extent of the allergic reaction and the number of different allergens to which the patient is sensitized. Nonallergic normal individuals have IgE concentrations that vary widely and increase steadily during childhood, reaching their highest levels at age 15 to 20, and thereafter remaining constant until about age 60 when they slowly decline.

PRINCIPLE

The test uses an anti-human IgE monoclonal antibody Ⅰconjugated with fluorescence latex coated on the sample pad, and another anti-human IgE monoclonal antibody Ⅱ coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human IgE monoclonal antibody Ⅰ binds with IgE in sample and forms a marked antigen-antibody complex. This complex moves to the test detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by the anti-human IgE monoclonal antibody Ⅱ. The fluorescence intensity of test line increases in proportion to the amount of IgE concentration in sample.

Then insert test card into Getein1100/Getein1160/Getein1180 Immunofluorescence Quantitative Analyzer/ Automatically inserted by Getein1200/Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100, Getein1160, Getein1180, Getein1200 and Getein1600), the concentration of IgE in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100/Getein1160/Getein1180 contains:

Package specifications: 25 tests/kit, 10 tests/kit

1) Getein Total IgE test card in a sealed pouch with desiccant
2) Disposable pipet
3) Sample diluent
4) User manual: 1 piece/kit
5) SD card: 1 piece/kit

2. A kit for Getein1200/Getein1600 contains:

Package specifications: 2×24 tests/kit, 2×48 tests/kit

Sealed cartridge with 24/48 Getein Total IgE test cards
User manual: 1 piece/kit

Materials required for Getein1200/Getein1600:

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, proteins, detergent, preservative, stabilizer.

4. A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad (coated with fluorescence latex-labeled anti-human IgE monoclonal antibody Ⅰ), nitrocellulose membrane (the test line is coated with another anti-human IgE monoclonal antibody Ⅱ, and the control line is coated with goat anti-mouse IgG antibody), absorbent paper and liner.

Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer
Getein1160 Immunofluorescence Quantitative Analyzer
Getein1200 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 Getein1100/Getein1160/Getein1180 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. For professional use only.
3. Do not use the kit beyond the expiration date.
4. Do not use the test card if the foil pouch or the cartridge is damaged.
5. Do not open pouches or the cartridge until ready to perform the test.
6. Do not reuse the test card.
7. Do not reuse the pipet.
8. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
9. 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.*** Heparin, sodium citrate and EDTA can be used as the anti-coagulant for plasma. Samples should be free of hemolysis.
2. Suggest using serum and plasma for better results. The test should be performed within 4 hours after blood collection.
3. If testing is delayed, serum and plasma samples may be stored up to 5 days at 2~8°C or stored at -20°C for 6 months before testing (whole blood samples 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 Getein1100/Getein1160/ Getein1180): 100 µL***

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should reach to room temperature before test.

For Getein1100:

1. Confirm SD card lot No. in accordance with test kit lot No. Perform “SD card” calibration when necessary.
2. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
3. Put the test card on a clean table, horizontally

placed.
4. 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.
5. ***Reaction time: 15 minutes.*** Insert the test card into Getein1100 and click on “Start” icon after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1160/Getein1180:

1. Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD card” calibration when necessary.
2. Enter testing interface of Getein1160/Getein1180.
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 Getein1200/Getein1600:

1. Each cartridge for Getein1200/Getein1600 contains a specific RFID card which can calibrate automatically.
2. Put the sample diluent at the correct position in Getein1200/Getein1600.
3. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1200/Getein1600 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 Getein1100/Getein1160/Getein1180.
3. Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1160/Getein1180/Getein1200/Getein1600.

Others: Measuring range of the Total IgE test kit is 1.00-2000.00 IU/mL. Dilute the sample which concentration is higher than the upper limit with negative samples, and the dilution ration should be less than 3 times.

EXPECTED VALUE

The expected normal value for total IgE was determined by testing samples from 240 apparently healthy individuals. The reference range of total IgE is 1.00 IU/mL~165.00 IU/mL calculated by using normal distribution methods(95% confidence interval).
It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	1.00-2000.00 IU/mL
Lower Detection Limit	≤1.00 IU/mL
Within-Run Precision	≤10%
Between-Run Precision	≤15%

LIMITATIONS

1. As with 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. Interferents in samples may influence the results. The table below listed the maximum allowance of these potential interferent.

Interferent	Hemoglobin	Triglyceride
Concentration (Max)	50 g/L	0.2 g/L

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DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Total IgE Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more detail 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
Σ	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 Total IgE Fast Test Kit (Immunofluorescence Assay).
Please read this user manual carefully before operating to ensure proper use.

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