Total IgE Rapid Quantitative Test

Catalog No.BT2901

INTENDED USE

The Biotime total IgE Rapid Quantitative Test is intended to quantify the concentration of total IgE (Immunoglobulin E) in human serum, plasma and whole blood, serum on Biotime FIA Analyzer by fluorescent immunoassay. The test is used as an aid detection of allergic diseases.
-Fluorescence immunoassay
-Allergic diseases
For in vitro diagnostic use only. For professional use only.

INTRODUCTION

Immunoglobulin E (IgE) is an antibody that is produced by the body's immune system in response to a perceived threat. It is one of five classes of immunoglobulins and is normally present in the blood in very small amounts. IgE is associated with allergic responses, including asthma, and to a lesser degree with immunity to parasites. IgE also has an essential role in type I hypersensitivity. An increased total IgE level indicates that it is likely that a person has one or more allergies. Allergen-specific IgE levels will increase after an exposure and then decline over time, thus affecting the total IgE level. An elevated level of total IgE indicates an allergic process is likely present, but it will not indicate what a person is allergic to. In general, the greater the number of things a person is allergic to, the higher the total IgE level may be. An IgE elevation can also indicate the presence of a parasitic infection but cannot be used to determine the type of infection [1-2].

PRINCIPLE

This test kit is based on fluorescent lateral flow immunoassay. While the sample and the buffer is mixed and applied into the test cartridge, the IgE in the sample and the mouse anti-IgE monoclonal antibody labeled with fluorescent microsphere form a reaction intermediate complex. During lateral flow, the intermediate complex moves along with the nitrocellulose membrane to a detection line (T-line: coated with IgE specific monoclonal antibodies). The intermediate complex will be captured by T-line to form final sandwich-like reaction complex. Thus the fluorescent signal on detection line is positively correlated with the concentration of total IgE in human serum, plasma and whole blood.

The fluorescent signal from microspheres of compound sandwich will be detected and calculated according to the calibration curve (in SD card provided with the reagents) to represent the concentration of total IgE in human serum, plasma and whole blood.

PRECAUTIONS

1. This reagent is used for in vitro diagnosis only, please do not use expired products.
2. All blood samples (including the remaining samples after testing), used reagents and waste should be treated as infectious materials.
3. The reagent is for one-time use. Once the pouch is opened, it should be used within 30 minutes to avoid failure caused by the moisture absorption.
4. While using the test cartridge and instruments, vibration and electromagnetic environment should be avoided.
5. Lot number of buffers and test cartridges must be matched.
6. Do not insert the cartridges that are contaminated with blood or other liquids on the surface. It may cause damages to the instrument.
7. IU/ mL×2.40=ng/mL.

MATERIAL

Material Provided
1. Test cartridge 25 tests/kit
2. Detection buffer 25 tubes/kit
3. SD Card 1 piece/kit
4. Instructions for use 1copy/kit

Material Required But Not Provided
1. Biotime FIA Analyzer
2. Transfer Pipette Set(range 5~50μL and 10~100μL size)
3. Specimen collection containers
4. Timer

STORAGE AND STABILITY

1. Store the detection buffer at 2-30℃, the shelf life is 24 months.
2. Store the test cartridge at 2-30℃, the shelf life is 24 months.
3. Test Cartridge should be used within 30 minutes after opening the pouch.

SPECIMEN COLLECTION AND PREPARATION

1. The test sample should be serum, plasma and whole blood. The specimen collection container shall be pro-coagulant or immune tube for serum and EDTA tube for plasma or whole blood.
2. Sample collection:
   a) The venipuncture for human serum/ plasma collection method referring to the National Clinical Laboratory Procedures, if the sample can't be detected timely, it can be stored in refrigerator at 2-8℃ for 6 days，or at -20℃ for 6 months.
   b) The venipuncture for human whole blood collection method referring to the National Clinical Laboratory Procedures, if the sample can't be detected timely, it can be stored in refrigerator at 2-8℃ for 7 days, free of freeze thawing.
3. Separate the serum/ plasma from blood as soon as possible to avoid hemolysis.

TEST PROCEDURE

Please refer to Biotime FIA Analyzer Operation Manual for the complete instructions on use of the Test. The test should be operated at room temperature（~25℃）.

Step 1: Preparation
Check/insert SD card into the equipment.
Take out one tube of buffer from refrigerator and balance it to room temperature.

Step 2: Sampling
For serum/ plasma: Take 20μL of serum/ plasma with a transfer pipette and add it to the buffer tube.
For whole blood: Take 30μL of whole blood with a transfer pipette and add it to the detection buffer tube.

Step 3: Mixing
Mix well the specimen with buffer by tapping or inverting the tube.

Step 4: Loading
Take 80μL of sample mixture and load it into the well of the test cartridge.

Step 5: Testing
Ensure that there are no air bubbles. Immediately insert the test cartridge into analyzer and incubate for 12 minutes.
NOTE: Please refer to the operation manual of a specific model of the analyzer for details.

REFERENCE INTERVAL

Normal Reference Value：

Age (years)	Normal Reference Value	
	IU/mL	ng/mL
neonates	＜1.5	＜3.6
<1	＜15.0	＜36.0
1-5	＜60.0	＜144.0
6-9	＜90.0	＜216.0
10-15	＜200.0	＜480.0
≥16	＜100.0	＜240.0

Note: Individual reference range is suggested to be established for each laboratory.

LIMITATIONS OF PROCEDURE

1. The test sample should be serum, plasma and whole blood.
2. Human anti-mouse antibody (HAMA) may be present in patients who have received immunotherapy with a murine monoclonal antibody. This kit has been specially designed to minimize the effect of these antibodies on the test results. However, the test result must be carefully evaluated when patients are known to have these antibodies[3-4] .
3. Other factors also can induce the false results, include the technology, operational error and other sample factors.

PERFORMANCE CHARACTERISTICS

Accuracy
Test cartridges from same lot were tested with total IgE control of three different levels of concentration, mean and Bias% were calculated, Bias% was within ±15.0%.

Assay Range: 1.0~5000.0IU/mL

The Lowest Detection Limit: 1.0IU/mL

Linearity
A serial concentrations of total IgE controls at 1.0~5000.0IU/mL were tested, the Correlation Coefficient (R) is≥0.9900.

Precision

Intra-Lot Precision
Intra-lot precision has been determined by using 10 replicates from same lot to test with total IgE control. The C.V. is ≤ 15.0%.

Inter-Lot Precision
Inter-lot precision was determined by testing of total IgE reference materials using 30 test cartridges from 3 consecutive batches randomly (10 test cartridges from each lot). The C.V. is ≤ 15.0%.

Specificity

Immunoglobulins	Concentrations	Test results
IgG	200.0mg/mL	≤1.0IU/mL
IgA	20.0mg/mL	≤1.0IU/mL
IgM	20.0mg/mL	≤1.0IU/mL

SYMBOLS

Symbol	Description	Symbol	Description
REF	Catalogue number	IVD	In vitro diagnostic medical device
LOT	Batch code		Consult instructions for use
	Date of manufacture		Keep dry
	Use-by date		Keep away from sunlight
	Manufacturer	2℃ 30℃	Store at 2-30℃
	Do not re-use	CE	CE mark
EC REP	Authorized representative in the European		

BIBLIOGRAPHY OF SUGGESTED READING

1. Erb KJ et al. Helminths, allergic disorders and IgE-mediated immune responses: where do we stand?. Eur. J. Immunol. 2007, 37 (5): 1170–1173.
2. Gould HJ, Sutton BJ, Beavil AJ, Beavil RL, McCloskey N, Coker HA, Fear D, Smurthwaite L. The biology of IGE and the basis of allergic disease. Annu. Rev. Immunol. 2003, 21: 579–628.
3. Hansen JH,et al. HAMA Interference with Murine Monoclonal Antibody-Based Immunoas says. J of Clin Immunoassay.1993, 16: 294-299.
4. Levinson SS. The Nature of Heterophilic Antibodies and the Role in Immunoassay Interference. J of Clin Immunoassay.1992, 15: 108-114.

Xiamen Biotime Biotechnology Co, Ltd.
Address: 2F/3F/4F/5F, No.188, Pingcheng South Road, Haicang Street, Haicang District, Xiamen City, Fujian Province, 361026, P. R. China.

EC REP
Lotus NL B. V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Tel: +31644168999

Version: A/06
Issuing date: 2024-04-01