Total IgE FIA Test | REF F5020 | Serum, Plasma, Whole Blood

For *in vitro* diagnostic use only. For professional use only.

INTENDED USE

The Total Immunoglobulin E (IgE) Fluorescence ImmunoAssay (FIA) Test is a lateral flow chromatographic fluorescence immunoassay for the quantitative detection of IgE in human serum, plasma, or whole blood using the *RaFIA* Immunofluorescence system. This test is intended for *in vitro* diagnostic use only.

SUMMARY AND EXPLANATION OF THE TEST

Immunoglobulin E (IgE) is an antibody synthesized by the immune system in response to a perceived threat. IgE plays an essential role in type I hypersensitivity, and it is also associated with allergic responses, including asthma, and to a lesser degree with immunity to parasites [1].

Total IgE levels vary according to the likelihood of a patient having one or more allergies. Allergen-specific IgE levels will increase after exposure and then decline over time. An elevated level of total IgE indicates that an allergic response is likely to be present, but it will not show which allergy the patient has.

In general, the more allergies a patient has, the higher the total IgE levels are. An IgE elevation can also indicate a parasitic infection but cannot be used to determine the type of infection [2].

TEST PRINCIPLE

This test is a fluorescent lateral flow immunoassay. When the specimen and the buffer are mixed and applied into the test device, the IgE present in the specimen and the mouse anti-IgE monoclonal antibody labeled with fluorescent reporters form an intermediate complex. The intermediate complex moves along the nitrocellulose membrane by lateral flow to a detection line (T-line) coated with IgE specific monoclonal antibodies. The intermediate complex will be captured by the antibodies coated on the T-line to form the final fluorescent reaction compound sandwich. Thus, the fluorescent signal on the detection line is positively correlated with the concentration of IgE in human serum, plasma, or whole blood.

The fluorescent signal from the reporters of the compound sandwich will be detected and calculated according to the calibration curve in the secure digital (SD) card (provided with the reagents), to represent the concentration of IgE in human specimens.

REAGENTS AND MATERIALS PROVIDED

1. Individually sealed foil pouches containing:
   a. One test device
   b. One desiccant
2. Detection buffer tubes
3. SD card
4. Instructions for Use

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock, watch or other timing device
2. *RaFIA* Immunofluorescence Analyzer
3. *RaFIA* Immunofluorescence Incubator

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied.

1. Store the detection buffer and test device at 2-30°C.
2. Use the test device within 30 minutes after opening the pouch.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

Step 1: Collect venous blood by venipuncture into a collection tube containing EDTA for plasma or whole blood specimens, or an immune or coagulation tube containing no anticoagulants for serum specimens.

Step 2: **For whole blood:** Test immediately or store refrigerated at 2-8°C for up to 24 hours after collection. Do not freeze specimens.

For plasma: Centrifuge the collected specimen and carefully withdraw the plasma into a new pre-labeled tube.

For serum: Allow blood to clot, centrifuge the collected specimen and carefully withdraw the serum into a new pre-labeled tube.

Step 3: **For Plasma/Serum only:** Test specimens immediately after collection or store refrigerated at 2-8°C for up to 5 days. Specimens can be frozen at -20°C for longer storage. Avoid multiple freeze-thaw cycles.

Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

Note: Do not test specimens demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference with result interpretation.

ASSAY PROCEDURE

Read these instructions and the instrument manual carefully before testing.

Please refer to the user manual of the *RaFIA* Immunofluorescence Analyzer and *RaFIA* Immunofluorescence Incubator for details.

Step 1: Bring the specimen and detection buffer to room temperature. If the specimen is stored frozen, thaw and mix well prior to performing the assay.

Step 2: Turn on the incubator. Set the incubation temperature to 25°C and incubation time to 12 minutes.

Step 3: Turn on the analyzer and insert SD card into the analyzer. Press "Test" and choose "Quick Test". Input the patient information, then press "Confirm".

Step 4: When ready to test, open the pouch and label the device with the specimen's ID number. Ensure that the lot number of the buffer and the test device match.

***Note:** Complete steps 5 and 6 within 1 minute to ensure the accuracy of the test results.*

Step 5: Add 20 µL of serum/plasma, or 30 µL of whole blood into the buffer tube. Mix the specimen well with detection buffer by tapping or inverting the tube.

Step 6: Load 80 µL of specimen mixture into the sample well of the device. Ensure that there are no air bubbles. Immediately insert the device into the incubator and incubate for 12 minutes.

Step 7: After 12 minutes, pull out the test device, insert it into the analyzer and press "Start Test". The test result will be shown on the screen and print automatically.

Step 8: Discard used devices after interpreting the result following local requirements governing the disposal of devices.

QUALITY CONTROL

Quality control tests are a part of good testing practices to confirm the expected results and validity of the assay, and should be performed at regular intervals or:

- After opening a new test lot to ensure the test performance is not altered.
- Whenever there is any question concerning the validity of the test results.

Control materials are not provided with this kit. For more information regarding obtaining the control materials, contact CTK Biotech's Sales Division for assistance (Please refer to the instructions for use of control material).

INTERPRETATION OF ASSAY RESULT

Expected Values

The following normal range is recommended. However, laboratories should establish their own diagnostic cut-off concentration based on the clinical practice at their respective institutions.

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

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PERFORMANCE CHARACTERISTICS

1. **Range**

   Working range: 1.0-1000.0 IU/mL

2. **Precision**

   Intra-lot Precision

   Intra-lot precision was determined by testing of IgE reference materials using 10 test devices from the same lot. CV ≤ 15%.

   Inter-lot Precision

   Inter-lot precision was determined by testing of IgE reference materials using 30 test devices from 3 consecutive lots randomly (10 test devices from each lot). CV ≤ 15%.

3. **Accuracy**

   IgE control materials with three different concentrations were tested by every lot of test device, and the deviations were within ±15%.

4. **Linearity**

   A serial concentration of IgE reference materials at 1.0-1000 IU/mL was tested, and the correlation coefficient (R) is ≥ 0.9900.

5. **Specificity**

   No cross reactivities were observed while testing following immunoglobulins with indicated concentrations:

Immunoglobulins	Concentrations	Test Results
IgG	200 mg/mL	≤ 1.0 IU/mL
IgA	20 mg/mL	≤ 1.0 IU/mL
IgM	20 mg/mL	≤ 1.0 IU mL

WARNINGS AND PRECAUTIONS

For *in vitro* diagnostic use only. For professional use only.

1. Read these Instructions for Use completely before performing the test. Failure to follow the instructions could lead to inaccurate test results.
2. Do not open the sealed pouch unless ready to conduct the assay. Do not use if the pouch is damaged or not sealed. Do not use expired devices.
3. Lot number of buffer and test device must match.
4. Bring all reagents to room temperature (15-30°C) before use.
5. Do not use components from any other type of kit as a substitute for the components in this kit. Use the Total IgE FIA Test in conjunction with CTK *RaFIA* instruments only.
6. Do not use hemolyzed blood specimens for testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other bloodborne pathogens.
9. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
10. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
11. Read test results at 12 minutes after a specimen is applied to the sample well of the device.
12. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.

LIMITATIONS OF TEST

1. Follow the assay procedure and the interpretation of assay result sections closely when testing for the presence of elevated IgE in serum, plasma, or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
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. If the symptoms are highly suspicious or persist, while the result from the Total IgE FIA Test is normal or non-reactive, it is recommended to test with an alternative test method.
4. Some unknown factors may interfere with the test and cause erroneous results, such as technical/procedural errors, degradation of the test components/reagents or presence of interfering substances in the specimens.
5. The Total IgE FIA Test should be considered a preliminary diagnostic tool only. In case of an abnormal result, consult a physician to discuss the test result and decide further course of action.

REFERENCES

1. Erb KJ et al. (2007). Helminths, allergic disorders and IgE-mediated immune responses: where do we stand? *Eur. J. Immunol.*, *37*(5): 1170–1173.
2. Gould HJ, Sutton BJ, Beavil AJ, Beavil RL, McCloskey N, Coker HA, Fear D, Smurthwaite L. (2003). The biology of IgE and the basis of allergic disease. *Annu. Rev. Immunol.*, 21: 579–628.
3. Hansen, H. J., Sharkey, R. M., Sullivan, C. L., & Goldenberg, D. M. (1993). HAMA interference with murine monoclonal antibody-based immunoassays. *J. Clin. Immunoassay*, *16*(4), 294-299.
4. Levinson, S. (1992). The nature of heterophilic antibodies and their role in immunoassay interference. *J. Clin. Immunoassay*, *15*, 108-115.

Index of Symbols

	Consult instructions for use	IVD	For *in vitro* diagnostic use only		Use by
REF	Catalog #	LOT	Lot Number	Σ N	Tests per kit
2°C 30°C	Store between 2-30°C		Do not reuse		
	Manufacturer		Date of manufacture		

CTK Biotech, Inc.
13855 Stowe Drive
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PI-F5020 Rev B1.1
Date released: 2021-12-21
English Version

For Export Only. Not For Resale in the USA.