IgE Rapid Test Cassette
(Whole Blood/Serum/Plasma)
Package Insert

A rapid test for the qualitative detection of human IgE antibodies in whole blood, serum or plasma specimen.
For professional in vitro diagnostic use only.

【INTENDED USE】

The IgE Rapid Test Cassette is a lateral flow chromatographic immunoassay for the qualitative detection of human IgE antibody in whole blood, serum or plasma to aid in the diagnosis of allergy.

【SUMMARY】

Immunoglobulin E (IgE) is a type of antibody (or immunoglobulin (Ig) "isotype") that has only been found in mammals. IgE is synthesised by plasma cells. Monomers of IgE consist of two heavy chains (ε chain) and two light chains, with the ε chain containing 4 Ig-like constant domains (Cε1-Cε4).[1] IgE's main function is immunity to parasites such as helminths[2] like *Schistosoma mansoni, Trichinella spiralis,* and *Fasciola hepatica.*[3,4,5] IgE is utilized during immune defense against certain protozoan parasites such as Plasmodium falciparum.[6]

IgE also has an essential role in type I hypersensitivity,[7] which manifests in various allergic diseases, such as allergic asthma, most types of sinusitis, allergic rhinitis, food allergies, and specific types of chronic urticaria and atopic dermatitis. IgE also plays a pivotal role in responses to allergens, such as: anaphylactic drugs, bee stings, and antigen preparations used in desensitization immunotherapy.

Although IgE is typically the least abundant isotype—blood serum IgE levels in a normal ("non-atopic") individual are only 0.05% of the Ig concentration,[8] compared to 75% for the IgGs at 10 mg/ml, which are the isotypes responsible for most of the classical adaptive immune response—it is capable of triggering the most powerful inflammatory reactions.

【PRINCIPLE】

The IgE Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative, lateral flow immunoassay for the detection of human IgE antibody in whole blood, serum or plasma specimens. In this test, mouse anti-human IgE is coated in the test line region of the test. During testing, IgE present in whole blood, serum or plasma specimen reacts with mouse anti-human IgE coated particles in the test strip. The mixture then migrates forward on the membrane by capillary action and reacts with the mouse anti-IgE on the membrane in the test line region. The presence of a colored line in the test line region indicates a positive result for IgE, while its absence indicates a negative result for that infection.

To serve as a procedural control, a colored line will always appear in the control line region of the strip indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test contains mouse anti-human IgE and human IgE antibody. A goat anti-mouse IgG is employed in the control line system.

【PRECAUTIONS】

1. For *in vitro diagnostic* use only. Do not use after the expiration date.
2. Do not smoke, drink, or eat in areas where specimens or kits reagents are handled.
3. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
4. Humidity and temperature can adversely affect results.
5. The used test should be discarded according to local regulations.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

- The IgE Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum and plasma specimen.
- Both Fingerstick Whole Blood and Venipuncture Whole Blood can be used.
- To collect **Fingerstick Whole Blood specimens:**
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test by using a **capillary tube:**
    - Touch the end of the capillary tube to the blood until filled to approximately 75μL. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well of the test cassette.
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. For long term storage, specimens should be kept below -20°C. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly for more than three times.
- If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.
- EDTA K2, Heparin sodium, Citrate sodium and Oxalate potassium can be used as anti-coagulants.

【MATERIALS】

Materials Provided

- Test Cassettes
- Droppers
- Buffer
- Package Insert

Materials Required But Not Provided

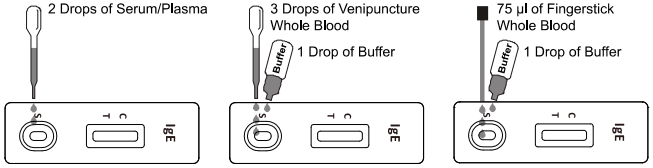
- Specimen Collection Containers
- Centrifuge (For plasma only)
- Timer
- Lancets (for fingerstick whole blood only)
- Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

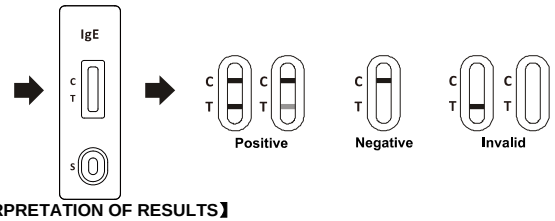
【DIRECTIONS FOR USE】

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within 1 hour.
2. Place the cassette on a clean and level surface.
   For **Serum or Plasma specimen**:
   Hold the dropper vertically and transfer **2 drops of serum or plasma (approximately 50μL)** to the specimen well, and start the timer. See illustration below.
   For **Venipuncture Whole Blood** specimen:
   Hold the dropper vertically and transfer **3 drops of whole blood (approximately 75μL)** to the specimen well, then add **1 drop of buffer (approximately 40μL)**, and start the timer. See illustration below.
   For **Fingerstick Whole Blood** specimen:
   Fill the capillary tube and transfer approximately **75μL of fingerstick whole blood** specimen to the specimen well of test cassette, then add **1 drop of buffer (approximately 40μL)** and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. Read results at **5 minutes**. Do not interpret the result after 10 minutes.

Note: It is suggested not to use the buffer, beyond 6 months after opening the vial.





【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE:* **Two colored lines appear**. One colored line should always appear in the control line region (C) and another line should be in the test line region.

***NOTE:** The intensity of the color in the test line region may vary depending on the concentration of human IgE antibodies present in the specimen. Therefore, any shade of color in the test line region should be considered positive.

NEGATIVE: **One colored line appears in the control line region (C)**. No line appears in the test line region.

INVALID: **Control line fails to appear**. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

Internal procedural controls are included in the test individually. A colored line appearing in control line region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The IgE Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for detection of human IgE antibody in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of IgE antibody can be determined by this qualitative test.
2. The IgE Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of IgE antibody in the specimen and should not be used as the sole criteria for the diagnosis of allergy was existed.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of allergy was existed.
5. This IgE Rapid Test is designed to work with hematocrit level between 25% and 65%. Performance of this test kit at a different hematocrit level can lead to erroneous results.

【EXPECTED VALUES】

The IgE Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with commercial other IgE Rapid tests, demonstrating an overall accuracy of 98.6%.

【PERFORMANCE CHARACTERISTICS】

Detection Limitation

The IgE Rapid Test Cassette (Whole Blood/Serum/Plasma) can detect totally IgE antibody as low as 200IU/ml.

Sensitivity and Specificity

The IgE Rapid Test Cassette (Whole Blood/Serum/Plasma) was compared with commercial other IgE Rapid tests; the results indicate that IgE Rapid Test Cassette (Whole Blood/Serum/Plasma) has a high sensitivity and specificity.

Method		Other Rapid Test		Total Results
IgE Rapid Test Cassette (Whole Blood/Serum/Plasma)	Results	Positive	Negative	
	Positive	125	4	129
	Negative	2	300	302
Total Results		127	304	431

Relative Sensitivity: 98.4% (95%CI*: 94.4%-99.8%) *Confidence Interval
Relative Specificity: 98.7% (95%CI*: 96.7%-99.6%)
Overall Accuracy: 98.6% (95%CI*: 97.0%-99.5%)

Precision

Intra-Assay

Within-run precision has been determined by using 3 replicates of four specimens: a negative, a low positive, a middle positive and a high positive. The negative, low positive, middle positive and high positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 3 independent assays on the same four specimens: a negative, a low positive, a middle positive and a high positive. Three different lots of the IgE Rapid Test cassette (Whole Blood/Serum/Plasma) have been tested over a 3-days period using negative, low positive, middle positive and high positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The IgE Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested for HBsAg, anti-HIV, anti-HCV, anti-RF, anti-Spyhilis, anti-H.pylori, anti-Toxo IgG, anti-Rubella IgG, anti-CMV IgG positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have also been tested using the IgE Rapid Test Cassette (Whole Blood/Serum/Plasma) and no interference was observed.

Acetaminophen: 20mg/dl	Caffeine: 20mg/dl	Creatine: 200mg/dl
Acetylsalicylic Acid: 20mg/dl	Gentisic Acid: 20mg/dl	Albumin: 2000mg/dl
Ascorbic Acid: 2g/dl	Hemoglobin: 1000mg/dl	Oxalic acid: 600mg/dl
Bilirubin: 1000mg/dL	Triglycerides: 1600mg/dl	Cholesterol: 800mg/dl

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