ACCUCARE®
IgE Rapid Card Test
(Whole Blood/Serum/Plasma)

A rapid test for the qualitative detection of human IgE antibodies in whole blood, serum or plasma specimen
Only for *In Vitro* diagnostic use.

ORDER INFORMATION

Pack Size	REF
10 Tests	IECC 10

CLINICAL SIGNIFICANCE

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 helminthes 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.

KIT COMPONENTS

• Test Cassettes • Droppers • Buffer • Package Insert • Alcohol Swab
• Lancet (for fingerstick whole blood only)

MATERIALS REQUIRED BUT NOT PROVIDED

• Specimen Collection Containers • Centrifuge (For plasma only) • Timer

PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Wear protective gloves while handling specimens wash thoroughly afterwards.
3. The device is sensitive to humidity as well as heat. Therefore, take out the device from seal pouch before test.
4. Do not mix reagents from different lot.
5. Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
6. Follow the testing procedure exactly as mention in the insert.

STORAGE AND STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test kit, if the pouch is damaged or seal is broken.

SPECIMEN COLLECTION & PREPARATION

The IgE Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum and plasma specimen.

- **Serum (S):** Collect the whole blood into a collection tube (NOT containing anticoagulants such as heparin, EDTA, and sodium citrate) by veinpuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
- **Plasma (P):** Collect the whole blood into a collection tube (containing anticoagulants such as EDTA K2, Heparin sodium, Citrate sodium and Oxalate potassium) by veinpuncture and then centrifuge blood to get plasma specimen.
- **Whole Blood (WB):** 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 sample well of the test cassette by using a sample dropper. Avoid air bubbles.
• 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.

DIRECTIONS FOR USE

Allow the test device, specimen and/or buffer to equilibrate at room temperature (15-30°C) before 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 1 drops of serum or plasma (approximately 25µL) and add 1 drop of buffer (approximately 40 µL) into the specimen well, and start the timer. See illustration below.
   For Venipuncture Whole Blood specimen: Hold the dropper vertically and transfer 1 drop of whole blood (approximately 25 µL) to the specimen well, then add 1 drop of buffer (approximately 40 µL), and start the timer. See illustration below.
   For Fingerstick Whole Blood specimen: Take sample using sample dropper and transfer approximately 25 µL of fingerstick whole blood specimen to the specimen well of test cassette, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. Read results at 5 minutes.
   Note: Do not interpret the result after 10 minutes.

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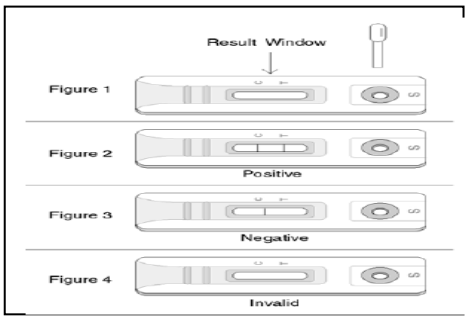
IgE Rapid Card Test
(Whole Blood/Serum/Plasma)

INTERPRETATION OF RESULTS



1) Positive
The control line (C) and test line (T) lines are visible on the test device. This is positive for human IgE antibodies. This is indicative of presence of Human IgE antibody
2) Negative
The control line is the only visible line on the test device. No human IgE Ab antibodies were detected
3) Invalid
The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the likeliest reasons for control line failure. Repeat the test using a new test device.

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 of the Test
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.

Detection Limitation
The IgE Rapid Test Cassette (Whole Blood/Serum/Plasma) can detect totally IgE antibody as low as 100IU/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 Test
IgE Rapid Card Test	Result	Positive	Negative	
	Positive	75	0	**75**
	Negative	0	230	**230**
Total Results		**75**	**230**	**305**

Sensitivity: >98% (95% CI*: 94.4%-99.8%) *Confidence Interval
Specificity: >98% (95%CI*: 96.7%-99.6%)

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 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. 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/d.l

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GLOSSARY OF SYMBOL

	Consult Instruction for Use	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer	IVD	For *in vitro* Diagnostic use only
	Keep away from sunlight	CONT	Content of the kit

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