Total IgE Rapid Test Device (Whole Blood/Serum/Plasma)

INTENDED USE

Total IgE Rapid Test device is an *in vitro* rapid immunochromatographic assay for the qualitative detection of total immunoglobulin E(IgE) in Whole Blood/Serum/Plasma specimens from patients. It is intended to aid in the presumptive diagnosis of allergy.

INTRODUCTION

Immunoglobulin E (IgE) is a class of antibody (or immunoglobulin (Ig) "isotype") that has been found only in mammals. IgE's main function is immunity to parasites such as parasitic worms like Schistosoma mansoni, Trichinella spiralis, and Fasciola hepatica. IgE may also be important during immune defense against certain protozoan parasites such as Plasmodium falciparum.

IgE also plays an essential role in type I hypersensitivity, which manifests various allergic diseases, such as allergic asthma, most types of sinusitis, allergic rhinitis, food allergy, and some types of chronic urticaria and atopic dermatitis. IgE also plays a pivotal role in allergic conditions, such as anaphylactic reactions to certain drugs, pollen, and antigen preparations used in specific 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, 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 inflammation reactions.

PRINCIPLE

The Total IgE Rapid Test Device is an immunochromatographic membrane assay to detect IgE in human Whole Blood/Serum/Plasma. Anti-IgE antibody, the test line, is adsorbed onto nitrocellulose membrane. Antibodies of the control line were adsorbed onto the same membrane as a second band. Anti-IgE antibodies are conjugated to visualizing particles that are dried onto an inert absorbent support.

During testing the sample is allowed to react with conjugate which was pre-adsorbed on the colored particles. The mixture then moves upward on the membrane by capillary action. As the sample flows through the test membrane, the coloured particles migrate. In the case of a positive result the specific antibodies present on the membrane will capture the IgE react with conjugate. The other immobilized antibodies also capture visualizing conjugate, forming the control line. A positive test result is read visually in 10-15 minutes or less depending on the concentration of IgE present in the specimen. A negative Total IgE Device result, read in 10 minutes, indicates that the concentration of IgE was below 100IU/ml.

The test is interpreted by the presence or absence of visually reddish color lines. A positive result will include the detection of both a test and control line, while a negative assay will produce only the control line. The control line does not appear, whether the test line is present or not, indicates an invalid assay.

MATERIALS

Materials Provided

- Device
- Pipette
- Instructions for use
- Buffer

Materials Required but Not provided

- Timer
- Specimen collection container

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Read the entire procedure carefully prior to testing.
- Used testing materials should be discarded according to local regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Care should be taken to protect the components of this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

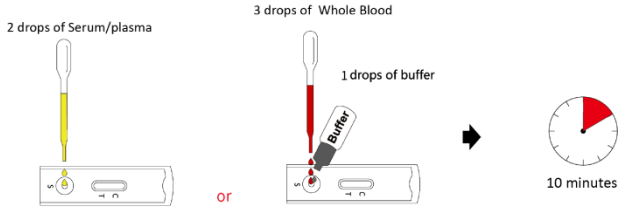
SPECIMEN COLLECTION AND STORAGE

- The Total IgE Rapid Test Device (Whole Blood/Serum/Plasma) is intended for use with human whole blood/serum/plasma specimens only.
- Only non-hemolyzed specimens are recommended for use with this test.
- Perform testing immediately after specimen collection. Do not leave 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. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Containers containing anticoagulants such as EDTA, citrate, or heparin should be used for whole blood storage.
- Bring specimens to room temperature prior to testing. If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

PROCEDURE

Bring tests, specimens, and/or controls to room temperature (15-30°C) before use.

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the test with patient or control identification. For best results, the assay should be performed within one hour.
2. For Serum or Plasma specimens: Hold the dropper vertically and transfer 2 drops of serum or plasma (approximately 50 µL) to the specimen well (S) of the test device, then start the timer..
   For Venipuncture Whole Blood specimens: Hold the dropper vertically and transfer 3 drops of venipuncture whole blood (approximately 75 µL) to the specimen well (S) of the test device, then add 1 drop of buffer(approximately 40µL) and start the timer.
   Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.
   As the test begins to work, color will migrate across the membrane.
3. Wait for the colored band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 15 minutes.



INTERPRETATION OF RESULTS

POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T). A positive result indicates that the sIgE concentration exceeds the detectable level.

NEGATIVE: Only one colored bands appears in the control region (C). No colored band appears in the test region (T). A negative result indicates that the sIgE concentration is below the detectable level.

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

1) The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region (T) should be considered positive. Please note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2) Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. 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 Total IgE Rapid Test Device (Whole Blood/Serum/Plasma) is for professional *in vitro* diagnostic use. Although the Test is very accurate in detecting IgE, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
2. Specimens from patients who have received mouse monoclonal antibodies for diagnostic or therapeutical use may contain human anti-mouse antibodies. Such specimens may show either elevated or depressed values when tested with assay kits that utilize mouse monoclonal antibodies.

PERFORMANCE CHARACTERISTICS

Sensitivity

The analytical sensitivity of the Total IgE Rapid Test is 100IU/mL

Accuracy

An evaluation of the IgE Test was performed to determine the clinical performance in comparison to another commercially available IgE ELISA test kit. A total of 183 patients were included in the study. The results of the study were as follows:

		IgE ELISA TEST		Total results
Ansure IgE Rapid Test		POSITIVE	NEGATIVE	
	POSITIVE	94	1	95
	NEGATIVE	2	86	88
Total Results		96	87	183

Relative Sensitivity: 97.9% (92.7%-99.4%)
Relative Specificity: 98.9% (93.8%-99.8%)
Overall Agreement: 98.4% (95.3%-99.4%)

LITERATURE REFERENCES

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GLOSSARY OF SYMBOLS

ρ	Catalog number	0	Temperature limitation
ι	Consult instructions for use	Λ	Batch code
I	In vitro diagnostic medical device	ε	Use by
µ	Manufacturer	T	Contains sufficient for <n> tests
σ	Do not reuse	A	Authorized representative in the European Community
Y	CE marking according to IVD Medical Devices Directive 98/79/EC		

µ
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