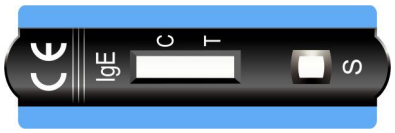
IgE TEST
004A610

ulti med IgE Test
For Finger Stick Whole Blood, Serum And Plasma



INTRODUCTION
An immunoglobulin E (IgE) immunological rapid test system is a device that contains reagents used to measure the immunoglobulin E (serum antibodies) concentration in whole blood, serum or plasma by immunochemical techniques. Measurement of these immunoglobulins aids in the diagnosis of abnormal protein metabolism, the body's lack of ability to resist infectious agents or autoimmune diseases.

INTENDED USE
The IgE test is a highly sensitive immunoassay for qualitative determination of human IgE in whole blood, serum, or plasma. This test is intended for professional use as an aid in the diagnosis and treatment of IgE-mediated allergic and autoimmune disorders. The sensitivity of the test is 80 IU/ml.

MATERIALS PROVIDED
- IgE test cassette with pipette in foil pouch (25 per kit box)
- 1 Instruction per kit box

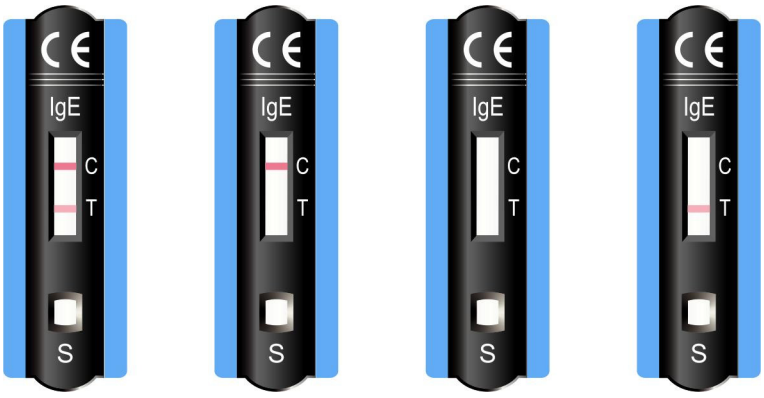
MATERIALS REQUIRED, BUT NOT PROVIDED
- Stop watch
- Alcohol pads
- Lancets

PRECAUTIONS
The IgE test kit must be stored at 4-30°C. The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test cassette from the foil pouch. Do not use it beyond the expiration date.

PROCEDURE OF THE TEST
1. Remove the test cassette from the foil pouch, and place it on a flat, dry and clean surface.
   Note: Once the test cassette is removed from the pouch, it should be used as soon as possible.
2. Clean the second or third finger by rubbing it with an alcohol pad.
3. Collect blood from the patient's finger. Massage near the puncture site to obtain blood flow.
4. Add 100 µl of blood (4 drops) into the Sample Well (S). Before adding the next drop, the previous one should be fully absorbed.
5. As the test begins to work, you will see a purple coloured front move across the Result Window in the centre of the test cassette.
6. Interpret test results at 10 minutes. Do not interpret test results after more than 15 minutes.

Caution: The above interpretation time is based on reading the test results at room temperature of 15 to 30°C. If your room temperature is significantly lower than 15°C, then the interpretation time should be properly increased.

INTERPRETATION OF THE TEST
- A coloured line will appear in the section of the Result Window marked with "C" to show that the test is working properly. This is the Control Line.
- The section of the Result Window marked with "T" indicates the test results. If another coloured line appears in this section it is the Test Line.



positive **negative** **invalid** **invalid**

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Positive Result: The presence of two coloured lines (“T” and “C”) in the result window regardless of which line appears first indicates a positive result (Figure 1). **Note:** Generally, the higher the IgE level in the specimen, the darker the “T” line colour will be. When the IgE level is close to but still within the sensitivity limit of the test, the colour of the “T” line will be very faint.

Negative Result: The presence of only one coloured line at “C” indicates a negative result (Figure 2).

Invalid Result: If after performing the test, no coloured line is visible in the Result Window, or only one line at “T”, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested (Figure 3 and 4).

Note: A positive result will not change once it has been established at 10 minutes. However, in order to prevent any incorrect results, the test result should not be interpreted after more than 15 minutes. When interpreting test results after more than 15 minutes, the sensitivity of the test will be higher than 80 IU/ml. Some specimens with a high rheumatoid factor concentration may yield a non-specific positive result.

LIMITATIONS OF THE TEST

Although the IgE 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.

WARNINGS

- The same lancet needle should be used for one person only and should not be shared with another person, because the used needle is a biohazard.
- Decontaminate and dispose of all specimens, reaction kits, lancet needle and potentially contaminated materials, as if they were infectious wastes, in a biohazard container.
- Do not use the kit after the expiration date.
- Do not use if pouch is torn or otherwise damaged.
- For in vitro diagnostic use only.

REFERENCES

- Hamilton RG and Adkinson MF, “Clinical Laboratory Methods for the Assessment and Management of Human Allergic Diseases,” Clin Lab Med, 1986, 6:117-38.
- Jeske DJ and Capra JD, “Immunoglobulins: Structure and Function,” Fundamental Immunology, Paul WE, ed, New York, NY: Raven Press, 1984, 131-65.
- Ownby DR, “Allergy Testing: In Vitro Versus In Vivo,” Pediatr Clin North Am, 1988, 35:995-1009.
- Van Arsdel PP Jr and Larson EB, “Diagnostic Tests for Patients With Suspected Allergic Disease,” Ann Intern Med, 1989, 110(4):304-12.
- Wall R and Kuehl M, “Biosynthesis and Regulation of Immunoglobulins,” Annu Rev Immunol, 1983, 1:393-422.

	Manufacturer		Contents sufficient for <n> tests
IVD	For in vitro diagnostic use only	LOT	Lot. no.
	For single use only		Use by
	Read instructions for use		Store at

Manufacturer:

ulti med Products (Deutschland) GmbH
Reeshoop 1 • 22926 Ahrensburg
Telefon: 04102 - 80090
Fax: 04102 - 50082
e-mail: info@ultimed.de

Sales / Export:

ulti med Products (Belgium) BVBA
Honzebroekstraat 137 • 8800 Roeselare
Phone: +32 +51 200 425
Fax: +32 +51 200 449
e-mail: belgium@ultimed.org

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