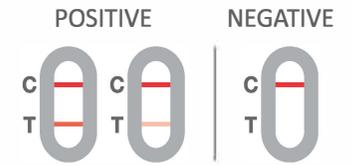


berkeleyhealth ALLERGY IgE

Self-test for the determination of total class E Immunoglobulins (IgE) in whole blood samples



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ALLERGIES AND IgE

Immunoglobulins E (IgE) are the class of antibodies that are most involved in allergic reactions. In normal conditions, IgE are present in blood in a really low quantity.

However, when they come in contact with the allergens, their concentration increases and they can trigger the cascade of reactions leading to the appearance of the main symptoms of an allergic reaction (such as skin erythema, itchiness, sneezing repeatedly, and, in some cases, anaphylactic shock).

This is why it is important to check if IgE levels are above normal, especially in people with a family history of allergies.

WHO ARE THE INTENDED USERS

ALLERGY IgE TEST is recommended to everyone with allergic reaction symptoms, such as itching and/or reddened skin, watery eyes and sneezing repeatedly.

WHY - BENEFITS

Checking the presence of IgE antibodies is useful to verify a potential general allergy reaction.

TEST PRINCIPLE

ALLERGY IgE TEST is an immunochromatographic test that detects the presence of IgE antibodies in the blood in concentrations above average, using special monoclonal antibodies conjugated with gold and integrated into the reactivestrip.

TECH SPECS

CUT-OFF	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
100 IU/mL	93.42%	91.42%	92.46%

Performance data obtained by clinical study with 146 participants enrolled. Immunocap Total IgE Thermofisher has been utilized as reference method.

CONTENT:

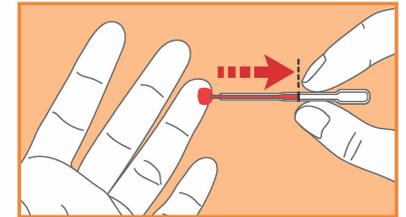
1 sealed aluminium pouch containing: 1 test device and 1 desiccant bag; 1 transparent plastic bag containing a pipette for blood collecting; 1 vial with dropper containing the diluent; 2 sterile lancets for blood sampling; 1 alcohol swab and 1 instructions for use leaflet.

CLINICAL EVIDENCES

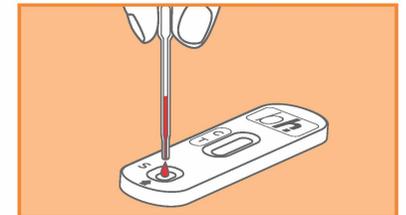
- Martins T.B., Bandhauer M.E., Bunker A. M., Roberts W. L.: "New childhood and adult reference intervals for total IgE." *Journal of Allergy and Clinical Immunology*. 2014;133(2):589-91.
- Chang M.L., Cui C., Liu Y.H., Pei L.C., Shao B.: "Analysis of total immunoglobulin E and specific immunoglobulin E of 3,721 patients with allergic disease". *Biomed Rep*. 2015 Jul;3(4):573-577.
- I. Leonard Bernstein, MD; James T. Li, et Al.: "Annals of allergy, asthma, & immunology." March 2008; Vol 100, num 3, supplement 3.

HOW TO USE IT

1) Take a blood sample after pricking the finger.



2) Deposit the sample into the specimen well of the cassette.



3) Add 2 drops into the well and wait 5 minutes before reading the result.

