

Total IgE Rapid Test

(Serum/Plasma/Whole Blood)

INTRODUCTION

IgE are the type of immunoglobulin in a body that fight with the specific infections or produced to response the antigen or allergy. The blood usually has a small amount of IgE antibodies. Higher amounts can be a sign that the body overreacts to allergens, which can lead to an allergic reaction. IgE levels can also be high when the body is fighting an infection from a parasite and from some immune system conditions or autoimmune response.

INTENDED USE

Rapid Test for Human IgE Device is a rapid chromatographic immunoassay for the semi quantitative determination of human IgE in whole blood, serum or plasma as a marker in the diagnosis of Allergic reactions.

This test is for healthcare professional use as well as for home use.

PRINCIPLE OF TEST

Rapid test for IgE Test Devices a semi quantitative, membrane-based immunoassay for the determination of IgE in whole blood, serum or plasma. The membrane is pre-coated with Anti-human IgE mAb on the test line region of the test. During testing, the whole blood, serum or plasma specimen reacts with the nanoparticle coated with anti-human IgE antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with capture Ab on the membrane and generate a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

CONTENTS OF KIT

1. Test Device with desiccant
2. Dropper.
3. Assay Buffer.
4. Package Insert.

OPTIONAL MATERIAL REQUIRED

1. Stopwatch

PRECAUTIONS/KIT STORAGE AND STABILITY

1. Please read all the information in this package insert before performing the test. Pay particular attention to the position of the Control and Test lines.
2. Do not use after the expiration date printed on the foil pouch.
3. Store in the sealed pouch in a dry place in between temperature 2°C to 30°C. Do not freeze.
4. Do not use if pouch is torn or damaged.
5. Do not open the foil pouch until you are ready to start the test.
6. Keep out of the reach of children.

WARNINGS

1. Do not reuse the test.
2. Follow the instruction to get accurate results.
3. Use appropriate personal protective equipment.
4. Dispose hygienically in domestic waste.
5. Do not touch the membrane.
6. Treat the samples and used test as potentially infectious. Avoid contact with skin.
7. For in vitro diagnostic use. Not to be taken internally.
8. Do not eat the desiccant in the package.
9. Do not mix the specimen sample or interchange the different specimen.
10. The manufacturer and distributor of this product shall not be liable for any losses, liability, claims, costs or damages whether director cons sequential rising out for related to an incorrect diagnosis.

SPECIMEN COLLECTION

Fresh anti coagulated whole blood should be used as a test sample. EDTA or Heparin or Oxalate can be used as suitable anticoagulants. Fresh serum or plasma can also be used as a test sample. The specimen should be collected in a clean glass or plastic container. If immediate testing is not possible then store the specimen at 2°C to 8°C for up to three days before testing. Clotted, contaminated or hemolyzed blood samples should not be used for performing the test.

Fresh finger pricked blood samples can also be used as a sample for testing.

LIMITATIONS

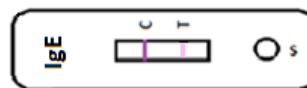
1. As with all diagnostic tests, the test result must always be correlated with clinical findings.
2. The results of test are to be interpreted within the epidemiological, clinical and therapeutic context. When it seems indicated, reference correlation should be considered.
3. Any modification to the above procedure and / or uses of other reagents will invalidate the test procedure.
4. The test is limited to the determination of IgE, 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.

TEST PROCEDURE

1. Bring the kit components to room temperature before testing.
2. Open the pouch and retrieve the test and desiccant pouch. Check the color of the desiccant. It should be blue, if it has turned colorless or pink, discard the test and use another test. Once opened, the test must be used immediately.
3. Label the test with patient's identity. Tighten the vial cap of the assay buffer provided with the kit in the clockwise direction to pierce the dropper bottle nozzle.
4. Keep the device on plain surface & add one drop (Approx.10µl) serum/plasma or two drops (Approx.20µl) whole blood sample in sample 'S' well by using dropper.
5. Add 2 drops of assay buffer in sample well "S".
6. Start the timer.
7. Read the result at 15 minutes. Do not read the result after 20 minutes.

INTERPRETATION OF RESULTS

Negative (Normal IgE): If colored line appears at control region 'C' & very faint or no colored band appears at test region T, then sample contains normal levels of IgE.



Positive (IgE higher than normal range): A distinct clearly visible colored line appears at control region 'C' and at the test region 'T', then specimen contains higher amount of IgE than normal range. Compare the intensity of colored line/band with color chart provide with kit. The intensity equivalent or similar to given concentration is the concentration of IgE in the sample.

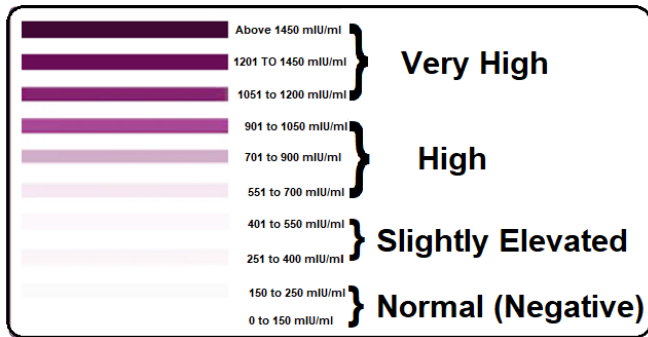
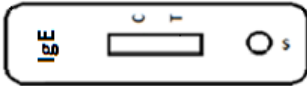


Invalid: Test should be considered invalid and repeat the test using fresh test if

- a. No line appears at control side 'C' and line appears only at test side 'T'.



- a. No line appears at control side 'C' and test side 'T'.



PERFORMANCE CHARACTERISTICS

Total 193 samples were evaluated for specificity & sensitivity. Sensitivity was found to be 100% (61/61) and relative specificity was found 100% (132/132).

Lowest detection limit is found to be 150 mIU/ml.

The Positive predictive value (PPV) and Negative Predictive value (NPV) for the test was 100 %.

No cross reactivity found with IgG, IgM, HCG, TSH, Bilirubin positive samples observed.

DISCLAIMER

The all precautions shall be taken to ensure the diagnostic ability and accuracy of this product. This product is utilized outside the control of manufacturer and distributors. The various factors including storage temperature, environmental conditions and procedure error may affect the results.