ECOTEST

Allergen-F1 Allergen (Egg White) Rapid Test Device

INTRODUCTION

The Allergen (Egg White) Rapid Test Device is a rapid test for the qualitative determination of Egg White specific immunoglobulin E (IgE) in human serum, plasma or whole blood.

The test is in conjunction with other clinical observations, in order to identify the patient whose allergic symptom may be mediated by Egg White specific immunoglobulin E (IgE) Type I hypersensitivity.

INTRODUCTION

Allergy is a common health problem, affecting approximately 20-25% of people. It is characterized by an abnormal response to allergens, where the immune system overreacts to harmless substances.

During an allergic reaction, the IgE antibody binds to the allergen, causing the release of histamine and other inflammatory mediators, leading to symptoms such as sneezing, runny nose, itching, and swelling.

The symptoms of allergy can vary from mild to severe, and can affect different parts of the body, including the skin, eyes, nose, throat, and lungs.

The diagnosis of allergy involves a combination of a patient history, physical examination, and laboratory tests.

PROCEDURE

Bring test strips, reagents, and controls to room temperature (15-30°C) before use.

1. Remove the test strip from its sealed pouch, and place it on a clean, level surface. Label the test with patient or control identification.

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 strip, and then start the timer.

3. For Whole Blood specimens: Hold the dropper vertically and transfer 3 drops of whole blood (approximately 200 μL) to the specimen well (S) of the test strip, and then add 1 drop of whole blood on the test strip, and then start the timer. Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.

4. As the test begins to work, color will migrate across the membrane. Look for the test band (T) to appear. Count the result normally at 15 minutes. Do not interpret the results 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 IgE concentration exceeds the detectable level.

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

QUALITY CONTROL

Initial procedural controls are included in the test. A colored band appearing in the control region

LIMITATIONS OF THE TEST

The Allergen (Egg White) Rapid Test Device is not intended for diagnostic purposes and should only be used for qualitative determination of IgE levels. The device is designed to confirm a specific IgE allergy. Sensitivity and specificities of the test need to be determined before using other clinical methods.

As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after clinical and laboratory findings have been evaluated.

SENSITIVITY

The analytical sensitivity of The Allergen (Egg White) Rapid Test is 0.70 μg/mL.

ACCURACY

A multi-center clinical evaluation was conducted comparing results obtained using The Allergen (Egg White) Rapid Test to another commercially available Allergen Rapid Test. The results of the study, which included 117 serum specimens, demonstrated 98.9% sensitivity and 99.3% specificity of The Allergen (Egg White) Rapid Test when compared to EIA.