Dia Sure

Allergen-F14

Allergen（Soybean） Rapid Test Device

INTENDED USE

The Allergen（Soybean） Rapid Test Device is a rapid test for the qualitative determination of Soybean specific Immunoglobulin E (sIgE) in human serum, plasma or whole blood.
The test, in conjunction with other clinicalobservations, is intended to identify the patient whose allergic symptoms maybe mediated by Soybean -specific immunoglobulin E (IgE) Type Ihypersensitivity.

INTRODUCTION

Allergy is a common health problem, affecting approximately 20-25% ofpeople with immediate-type hypersensitivity reactions that manifest in theform of rhinitis, urticaria, dermatitis, gastrointestinal illness, wheezing andrarely anaphylactic shock. The term allergy is often used for type Ihypersensitivity reactions (immediate typereactions), whose symptoms generally occurwithin 30-60 minutes after contact with theallergen.
The allergens causing type I hypersensitivityreactions are mostly proteins derived from thenatural environment e.g. plant pollen, animalhair, food, mites, and insect venoms.A characteristic of type I allergies is theinvolvement of allergen specific immunoglobulins(antibodies) of class E (sIgE). Hence,the detection of sIgE is an important tool ofmodern allergy diagnostics.
Soybean allergy is one of the more common food allergies, especially among babies and children. Approximately 0.4 percent of children are allergic to soy. Studies indicate that an allergy to soy generally occurs early in childhood and often is outgrown by age three. Research indicates that the majority of children with soy allergy will outgrow the allergy by the age of 10.

PRINCIPLE

The Allergen（Soybean） Rapid Test Device has been designed to detect Soybean sIgEthrough visual interpretation of color development in the internal strip. The membrane was immobilized with streptavidinon the testregion, the conjugate pad was pre-coated with coloredanti-IgE antibody colloidal gold conjugates and the sample pad was pre-coated with biotinylatedSoybeanProtein. After specimens were added, the gold-conjugates move along the membrane chromatographically by capillary action and antibodies get to the test region. If sufficientSoybean sIgE is present in the sample, it will react with biotinylated Soybean protein in sample pad, the mixture then migrates through conjugate pad by capillary action and interact with coloredanti-IgE antibody colloidal gold conjugates, form a complex. Then the complex moves to the membrane, and combine with streptavidin. As a result, a colored band will form at the test region of the membrane.
If no Soybean sIgE is present in the sample, biotinylated allergen pre-coated on the sample pad will bind to streptavidin immediately, so there is no colored line at the test region of the membrane.
Therefore, the colored band on the test region indicates a positive result. And appearance of a colored band at the controlregion serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Materials Provided

- Individually packed test devices
- Disposable pipettes
- Package insert
- Whole blood buffer

Materials Required but Not provided

- Specimen collection container
- Timer

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 or canister is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is, therefore, recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.

STORAGE AND STABILITY

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

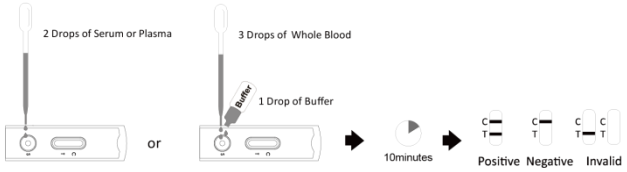
SPECIMEN COLLECTION AND STORAGE

- The Allergen（Soybean） Rapid Test Device is intended for use with human whole blood, serum and plasma only.
- Only clear, non-hemolyzed specimens are recommended for use with this test. Serum or plasma should be separated as soon as possible to avoid hemolysis.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. 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.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- 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.

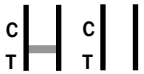
1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the test with patient or controlidentification. For best results, the assay should be performed within one hour.
2. For Serum or Plasma specimens: Hold the dropper vertically and transfer 2 drops of serum or plasma (approximately 50 µL) to the specimen well (S) of the test device, then start the timer..
   For Whole Bloodspecimens: Hold the dropper vertically and transfer 3 drops of whole blood (approximately 75µL) 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. Read the result visually at 10min. 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 appearsin 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

- The Allergen（Soybean） Rapid Test Device is for professional in vitro diagnostic use, and should be only used for the qualitative detection of allergen sIgE.
- The Allergen（Soybean） Rapid TestDevice will only indicate the presence of sIgE in the specimen and should not be used as the sole criteria for the diagnosis of Allergy.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended.
- As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
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PERFORMANCE CHARACTERISTICS

Sensitivity
The analytical sensitivity of The Allergen（Soybean） Rapid Test is 0.7IU/mL

Accuracy
A multi-center clinical evaluation was conducted comparingresults obtained using The Allergen（Soybean） Rapid Test toanother commercially available Allergen Rapid Test. Theresults of the study, which included 129serum specimens,demonstrated 97.7% accuracy of The Allergen（Soybean） Rapid Test when compared to EIA

Allergen(Soybean) Rapid Test vs. EIA

Method		EIA		Total results
Allergen（Soybean） Rapid Test	Results	Positive	Negative	
	Positive	43	2	45
	Negative	1	83	84
Total Results		44	85	129

Relative Sensitivity: 97.7% (88.2%-99.6%)
Relative Specificity: 97.6% (91.8%-99.4%)
Overall Agreement: 97.7% (93.4%-99.2%)

Interference Testing
The following substances were added to Soybean sIgE free serum and serum samples spiked with 0.7IU/mL Soybean sIgE. None of the substances interfered with the assay at the listed concentrations.

Acetaminophen	20 mg/dL	Acetylsalicylic Acid	20 mg/dL
Ascorbic Acid	20 mg/dL	Atropine	20 mg/dL
Caffeine	20 mg/dL	Gentisic Acid	20 mg/dL
Glucose	2 g/dL	Hemoglobin	1 mg/dL

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		

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