

4. Interpretation of Results

15 minutes after application of the allergen extracts, interpret the positive and negative controls to confirm the reliability of the test. Any wheal (raised swelling) size and erythema/ flare (redness) relative to controls should be recorded in millimeters. Typically, any result larger than the control can indicate the presence of specific IgE antibody. However, a raised wheal 3mm or 10mm flare can be interpreted as a positive result. For accuracy and repeatability record results on an appropriate form for retention in the patient's file. (Medscience can provide you with a recording form that corresponds to the ST-9® Multiple Allergen Test Tray array.) Typically, the following interpretations can be made from the measurement:

- A positive skin test is a wheal (raised swelling) >3mm and/or an accompanying flare (surrounding redness) of ≥10mm.
- A flare ≥10mm without an accompanying wheal may also be considered a positive response.

5. Completion of the Test

Once the test has been completed the patient's skin should be cleaned of any excess allergenic extracts with an alcohol swab or simple soap and water. If the allergic reactions have been significant it may prove advisable to apply an anti-histamine cream to the test area.

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⚠ **CAUTION:** This device is restricted by Federal Law to be used by or under order of a licensed physician or nurse practitioner.
⚠ **CAUTION:** You must observe all the cautions and procedures contained in package insert for contraindications, intervals relating to drug administration and application of the test.
⚠ **CAUTION:** Sterility of the ST-9® Applicator is only assured if the package is unopened and undamaged.
Package Contents: The ST-9® Multiple Skin Test Applicator is supplied in a package of 8 or 4 sterile applicators, **Item No. 1000**. Individual packages of **Item 1000** can be packed in various quantities, such as 10, 15, 30, 32 or 42 to the case. The ST-9® Multiple Test Tray is packaged as one sterile test tray as **Item No. 1001**, having 72 test wells or **Item 1001-36**, having 36 test wells.

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MedScience®
Directions for Use
of the
ST-9® Skin Test Applicator
and
ST-9® Multiple Well Test Tray

Introduction

Allergies affect approximately 1 in 5 Americans, making allergies one of the most common health problems. Allergies result in more than 17 million physician visits, 30,000 emergency visits and hundreds of deaths annually. Increasing global temperatures are predicted to increase pollen and related air borne allergens in the coming years and therefore the number of allergy sufferers. Allergies increase a person's risk of other diseases including asthma.

Allergies

An allergy is a hypersensitivity disorder of the immune system. Allergic reactions occur when a person's immune system reacts to normally harmless substances in the environment. A substance that causes a reaction is called an allergen. These reactions are acquired, predictable, and rapid. Allergy is one of four forms of hypersensitivity and is formally called type I (or immediate) hypersensitivity. Allergic reactions are distinctive because of excessive activation of certain white blood cells called mast cells and basophils that produce a type of antibody called Immunoglobulin E (IgE). This reaction results in an inflammatory response which can range from uncomfortable to dangerous.

Prevalence

There is credible scientific evidence indicating higher incidence of allergy occurring today than ever before. A recent report showed 54 percent of people between five and fifty-nine years of age had a positive test to at least one or more common allergens. Due to only 10 common allergens tested in this study the reported percentage is likely to be an underestimation of the actual prevalence of allergic sensitization in the US population. This represents 139 million Americans have potential to suffer from allergies. Further, figures from the National Center for Health Statistics, in their most recent report, indicate that the number of asthma cases in the United States jumped 74 percent from 1980 to 1996. Moreover, it is known that an allergic reaction can be caused by the cumulative effect of several allergens being present concurrently, neither of which on its own would cause an allergic reaction.

Impact

The annual cost of allergies is said to be nearly incalculable, given the number of doctors' visits, pharmaceutical prescriptions, lost work and the intangible agonies that each allergy sufferer endures. In some patients, the degree of allergic reaction has caused significant life style changes or even overwhelming restrictions in activity.

Testing

Skin tests have evolved as reliable, cost effective techniques for the identification of Immunoglobulin E (IgE) mediated diseases. The technique, originally involving the placement of an allergen on abraded skin began in 1867, has now progressed to the utilization of technology to administer a known amount of allergen via percutaneous (on the skin) scratch. This allows the clinician to confirm clinical sensitivity to a range of allergens, such as pollens, weeds, grasses, trees, animal dander, molds and many foods.

Back Cover

Front Cover

Quality & Reliability

Although generally age, sex, and race are independent, certain age (children younger than 2 years and adults older than 65 years) and racial (African American children) factors may affect interpretation. Positive (histamine) and negative (saline or 50% glycerinated–saline) should be performed at the same time as allergen tests to establish a base line for measuring reactions.

The Patient's Medications

A complete medical history should be collected, and especially the patient's current intake of medications. Several classes of drugs can interfere or distort the outcome of an allergy test, because of their antihistamine effect. Antihistamines type drugs vary considerably in their ability to suppress a patient's test response, therefore the use of first- and second-generation antihistamines should be discontinued 3 to 10 days before skin tests with notable exceptions, such as cetirizine, hydroxyzine, demastine, loratadine, and cyproheptadine. The tricyclic antidepressant doxepin may also suppress the wheal-and-flare response for as long as 6 days. Histamine2 antagonists may cause mild suppression, and their use should be discontinued at least 24 hours before testing. Oral prostaglandin D2 inhibitors, (e.g., indomethacin) given several hours before testing may cause a slight increase in the patient's response to the allergen. Skin tests should be avoided in sites where corticosteroids have been applied or application ceased for 2 to 3 weeks before testing. See the table below for the summary of recommended intervals between administration of the drug and testing.

Recommended intervals between drug administration & testing

First-generation antihistamines	3 days
Second-generation antihistamines	7-10 days
Cyproheptadine	14 days
Ketotifen	60 days
Astemizole	7-10 days
Neuroleptics	7-10 days
Anti-psychotic drugs (tricyclic antidepressants)	3 days

Testing Site

The preferred test site is the upper back, although the volar surface of the forearms can also be used. Skin tests should not be performed in skin sites with active dermatitis or severe dermatographism. If they are performed in the presence of mild dermatographism, the results should be interpreted with caution.

Safety

The Patient

Adverse events occurring post percutaneous tests are rare but can occur. Large local reactions, both immediate and late, may cause discomfort and occasionally mild, non-progressive systemic reactions may be associated with the latter. To reduce the likelihood of adverse reactions during skin testing, several precautions should be taken. Pre-screening with a detailed medical history should be performed that investigates recent use of medications (see above), history of allergic reactions, history of skins disorders / complaints and tolerance to certain foods / drugs.

The Clinician

It is imperative the clinician comply with OSHA's Blood Born Pathogen standard: http://www.osha.gov-pls/oshaweb/owadisp.show_document?p_table=standards&p_id=10051

Indication for Use

The skin test applicator is used for conventional administration (percutaneous application of allergenic extracts directly onto the surface of the skin) of diagnostic allergen extracts for performing allergy skin tests on the typical sites (the back and the volar surfaces of the forearms) for hypersensitivity reactions in individuals suspected of having allergies. The test tray is intended to hold allergenic extracts in a convenient arrangement for storage and use by the clinician.

Contraindications

If the following conditions are present the test should not be performed:

Contraindications to percutaneous allergy testing

- a. Anaphylactic reaction (constitutional) after the previous skin test with the same allergen
- b. Acute fever
- c. Systemic disease with acute manifestation or decompensation
- d. Abnormal skin condition in the area to be tested (such as eczema, condition after sunbathing)
- e. Children younger than 3 years
- f. Pregnancy

Application of Test

To achieve the most accurate results it is recommended that the following technique be developed and performed. This will ensure sufficient contact with the skin and the device is achieved allowing the test heads of the applicator to deliver the allergenic extracts to the reactive epidermis layer of the skin. The ST-9® Skin Test Applicator is designed to perform percutaneous skin tests for the diagnosis of allergic reactions by applying various allergenic extracts to a patient's skin. The device is sterile and must be disposed of after each use. The following procedure should be followed.

1. Prepare Device & Materials

- Layout the ST-9® Multiple Well Test Tray, the allergen reaction scale, a test report form and have ready access to a biohazard container. It is assumed that the physician has filled the wells with the suitable allergenic extracts prior to use in the test. **See Figure 1.**
- Open a package of sterile ST-9® Skin Test Applicators and place an applicator in each of the test wells in the testing tray.



Figure 1.

Test Tray

2. Prepare the Patient

Preparation of testing site

Clean the patient's upper back or the volar surfaces of the forearms thoroughly with alcohol. The skin must be clean, dry and free of any signs of hyperemia.

3. Performing the test

- a. Remove the first ST-9® Skin Test Applicator from the multiple well test tray
- b. Hold the applicator perpendicular to the skin.
- c. Press down on skin with moderate pressure (depress skin at least 1mm).
- d. Without lifting, rock the device side to side, then top to bottom. ¹(The process of applying each test applicator, as described, should not take more than 3 to 5 seconds.)
- e. Remove applicator from skin (when performed properly the device will leave visible marks on the skin without bleeding)
- f. Discard the applicator in the biohazard container
- g. Repeat the procedure with the desired number of applicators, disposing of each applicator after each use. **See Figure 2**



Figure 2.

- Upon completion of each test panel the applicator should be discarded in accordance with the governing regulations. **DO NOT REUSE AN APPLICATOR. When the prescribed test is completed and the applicators disposed of properly, seal the tray with its locking lid and return it to the refrigerator between any extended testing sessions.**