Allergy Services
for Your Practice
The Allergic Disease

A nationwide problem affecting approximately 20% of the population, or 65 million people.

The statistics are staggering:

Annually, allergies and asthma impact the US drastically:

- Allergic Rhinitis is the 6th most prevalent chronic disease amongst adults and the most common in children.
- Annual medical costs are 46% higher in patients with associated asthma and allergic rhinitis.
- In any given 12-month period there are:
  - 14 million lost school days
  - 20 million missed work days
  - 20 million outpatient visits
  - 1.8 million ER visits
  - 5,000 deaths

- 90% of patient who report as penicillin allergic are not when tested.
- The average cost for patients with a beta-lactam allergy is up to 63% higher compared to those without.
Does allergy complicate the diagnosis of your patients?

It is estimated that 50% of patients visiting ENT offices suffer from allergies. It has been suggested, the relationship between allergic disease and many head and neck diseases is crucial. This could present in a variety of ways and may affect the diagnosis due to overlapping symptoms.

Allergy, as a part of a complete evaluation, becomes a key in a variety of factors:

- Is allergy a differential diagnosis from their original complaint?
- Are patient concerns being neglected by not thoroughly evaluating an allergy diagnosis?
- Would identifying and treating specific allergies optimize results?
- Could treatment options be limited for the patient without a proper evaluation of potential penicillin allergy?

40-50% of children with tubes have positive allergy tests.

Penicillin is the drug of choice for many infections such as sinusitis.

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Adding the allergy diagnosis and treatment suite of services to your practice is easier than you may think and can be implemented slowly or all at once.

Three steps to consider:

1. **Penicillin Allergy Testing**
   - Penicillin allergy skin testing is the first suggested step in adding allergy services to your practice. Implementing penicillin allergy skin testing may properly diagnose penicillin allergic patients, allowing for additional treatment options.

2. **Complete Allergy Diagnosis**
   - Allergy may play a significant role when patients complain of head and neck conditions. Proper diagnosis with skin testing may confirm the suspicion of allergies, correctly identify the most problematic allergens and determine the severity.

3. **Allergy Treatments**
   - Allergy immunotherapy is a clinically documented treatment that may reduce or completely remove allergy symptoms and the need for traditional symptom-relieving medication. This kind of treatment has been in use worldwide for over 100 years.
When planning to initiate allergy services, the proper foundation is the key to success. There are many areas to consider to get started:

**ALK is your one source partner for your allergy services.**

ALK provides comprehensive allergy solutions so you can focus on your patients instead of the administrative side of your practice. From an extensive selection of allergy extracts, skin testing devices, and allergy practice automation software to customized business, technical and clinical consulting services, we are committed to helping your practice grow so you can improve the lives of more allergic patients.

In addition to supporting your practice, we also support the allergic patient.

Our Fight the Cause partnership is focused on generating awareness of the allergy epidemic and increasing the number of lives improved by Fighting the Cause of allergies instead of only treating the symptoms.

Go to www.fightthecauseofallergy.org to learn more.
Partner with an allergy company that supports your business and your specialty.

We provide the supplies you need to equip your allergy practice, services to optimize your practice, and programs that support your business and the immunotherapy industry.

**Scientific Leadership**
ALK is the world’s largest allergenic extract manufacturer with global resources focused solely on allergens, extract manufacturing, and allergen-specific immunotherapy.

**ALK Advantage Program**
Our advantage program provides valuable business benefits to our loyal customers. This program is intended to expand your staff’s knowledge of the administration of immunotherapy as well as provide supplementary patient education materials including: hand-outs, posters, and DVDs.

**Allergy Supplies**
- **Full Line of Allergenic Extracts**: ALK offers over 150 different allergens for testing and treating your patients.
- **Skin Testing Devices**: Multi-Test®II, Multi-Test® PC, Duotip-Test®II and UniTest® PC provide multiple and single testing options for rapid and precise allergy skin testing.
- **Sterile Empty Vials, Diluent, and Syringes**: A large selection of ancillary products available, offered at competitive prices.
- **Penicillin Allergy Skin Testing**: ALK currently offers the only FDA approved penicillin allergy test.
Increase productivity and profitability with the help of our customized consulting services.

**Business Consulting**
Services include but are not limited to:
- Business plan development, profitability analysis and clinic operation enhancements
- Marketing consulting including direct mail, website reviews, digital marketing, and patient education materials
- Tools to strengthen your referral network.

**Clinical Consulting**
Our professional allergy nurse consultants provide on-site training for nurses new to allergy or experienced nurses who would like to be updated with the latest standards including:
- Patient safety, clinic operations and efficiency
- Mixing patient vials
- Skin testing and administering injections

**Technical Consulting**
Our Scientific Services Team will provide answers to questions regarding:
- Clinical studies on Immunotherapy
- Standardization, cross-reactivity and regional allergens
- Custom allergen panel reviews

ALK Makes It Easy to Get Started with Packages including:

**Products**
- Penicillin Allergy Testing
- 48 Allergen Diagnostic Panel Specific to Your Region
- Skin Testing Devices and Other Necessary Supplies

**Services**
- Practice Marketing
- Referral Building
- Nurse Training
- Scientific Support
- Business Optimization
PRE-PEN® - benzylpenicilloyl polylysine injection, solution
Skin Test Antigen

DESCRIPTION:

PRE-PEN® (benzylpenicilloyl polylysine injection USP) is a sterile solution of benzylpenicilloyl polylysine in a concentration of 6.0 X 10⁻⁵ M (benzylpenicilloyl) in 0.01 M phosphate buffer and 0.15 M sodium chloride. The benzylpenicilloyl polylysine in PRE-PEN is a derivative of poly-L-lysine, where the epsilon amino groups are substituted with benzylpenicilloyl groups (50-70%) forming benzylpenicilloyl alpha amide. Each single dose ampule contains 0.25 mL of PRE-PEN.

PRE-PEN has the following structure:

```
    CH2CH2CONHCH2CONHCH2CONHCH2CONHCH2CONHCH2CONHCH2CONH
        |                  |                  |                  |                  |
        NH2                NH2                NH2                NH2                NH2
        |                  |                  |                  |                  |
        CH2CH2OH            CH2CH2OH            CH2CH2OH            CH2CH2OH            CH2CH2OH
```

Where “a” is an integer greater than 40 and “b” is

Benzylenzilpenicilloyl

CLINICAL PHARMACOLOGY:

PRE-PEN is a skin test antigen reagent that reacts specifically with benzylpenicilloyl IgE antibodies initiating the release of chemical mediators which produce an immediate wheal and flare reaction at a skin test site. All individuals exhibiting a positive skin test to PRE-PEN possess IgE against the benzylpenicilloyl polylysine structural group which is a hapten. A hapten is a low molecular weight chemical that conjugates with a carrier (e.g. poly-L-lysine) resulting in the formation of an antigen with the hapten’s specificity. The benzylpenicilloyl hapten is the major antigenic determinant in penicillin-allergic individuals.

However, many individuals reacting positively to PRE-PEN will not develop a systemic allergic reaction on subsequent exposure to therapeutic penicillin, especially among those who have not reacted to penicillins in the past. Thus, the PRE-PEN skin test determines the presence of penicilloyl IgE antibodies which are necessary but not sufficient for acute allergic reactions due to the major penicilloyl determinant.

Non-benzylpenicilloyl haptenes are designated as minor determinants, since they less frequently elicit an immune response in penicillin treated individuals. The minor determinants may nevertheless be associated with systemic clinical hypersensitivity. PRE-PEN does not react with IgE antibodies directed against non-benzylpenicilloyl haptenes.

INDICATIONS AND USAGE:

PRE-PEN is indicated for the assessment of sensitization to penicillin (benzylpenicilloyl or penicilloyl G) in patients suspected to have clinical penicillin hypersensitivity. A negative skin test to PRE-PEN is associated with an incidence of immediate allergic reactions of less than 5% after the administration of therapeutic penicillin, whereas the incidence may be more than 50% in a history-positive patient with a positive skin test to PRE-PEN. These allergic reactions are predominantly dermatologic. Whether a negative skin test to PRE-PEN predicts a lower risk of anaphylaxis is not established. Similarly, when deciding the risk of proposed penicillin treatment, there are not enough data at present to permit relative weighing in individual cases of a history of clinical penicillin hypersensitivity as compared to positive skin tests to PRE-PEN and/or minor penicillin determinants.

CONTRAINDICATIONS:

PRE-PEN is contraindicated in those patients who have exhibited either a systemic or marked local reaction to its previous administration. Patients known to be extremely hypersensitive to penicillin should not be skin tested.

WARNINGS:

The risk of sensitization to repeated skin testing with PRE-PEN is not established. Rarely, a systemic allergic reaction including anaphylaxis (see below) may follow a skin test with PRE-PEN. To decrease the risk of a systemic allergic reaction when retesting skin testing should be performed first. Intradermal skin testing should be performed only if the puncture test is entirely negative.

PRECAUTIONS:

General:

No reagent, test, or combination of tests will completely assure that a reaction to penicillin therapy will not occur. The value of the PRE-PEN skin test alone as a means of assessing the risk of developing therapeutic penicillin (when penicillin is the preferred drug of choice) in the following situations is not established:

1. Adult patients who give no history of clinical penicillin hypersensitivity.

2. Pediatric patients.

In addition, the clinical value of PRE-PEN where exposure to penicillin is suspected as a cause of a current drug reaction or in patients who are undergoing routine allergy evaluation is not known. Likewise, the clinical value of PRE-PEN skin tests alone in determining the risk of administering semi-synthetic penicillins (phenoxymethyl penicillin, ampicillin, carbenicillin, dicloxacillin, methicillin, nafcillin, oxacillin, amoxicillin), cephalosporin-derived antibiotics, and penem antibiotics is not known.

In addition to the results of the PRE-PEN skin test, the decision to administer or not administer penicillin should take into account individual patient factors. Healthcare professionals should keep in mind the following:

1. A serious allergic reaction to therapeutic penicillin may occur in a patient with a negative skin test to PRE-PEN.

2. It is possible for a patient to have an anaphylactic reaction to therapeutic penicillin in the presence of a negative PRE-PEN skin test and a negative history of clinical penicillin hypersensitivity.

3. If penicillin is the drug of choice for a life-threatening infection, successful desensitization with therapeutic penicillin may be possible irrespective of a positive skin test and/or a positive history of clinical penicillin hypersensitivity.

Pregnancy — Pregnancy Category C:

Animal reproduction studies have not been conducted with PRE-PEN. It is not known whether PRE-PEN can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. The hazards of skin testing in such patients should be weighed against the hazard of penicillin therapy without skin testing.

ADVERSE REACTIONS:

Occasionally, patients may develop an intense local inflammatory response at the skin test site. Rarely, patients will develop a systemic allergic reaction, manifested by generalized erythema, pruritus, angioedema, urticaria, dyspnea, hypotension, and anaphylaxis. The usual methods of treating a skin test antigen-induced reaction — the applications of a venous occlusion tourniquet proximal to the skin test site and administration of epinephrine are recommended. The patient should be kept under observation for several hours.

DOSE AND ADMINISTRATION:

SKIN TESTING DOSAGE AND TECHNIQUE

Skin testing is usually performed on the inner volar aspect of the upper, outer arm, sufficiently below the deltoid muscle to permit proximal application of a tourniquet later, if necessary. Be sure to eject all air from the syringe through the needle, then insert the needle, bevel up immediately below the skin surface. Inject an amount of PRE-PEN sufficient to raise a small intradermal bleb of about 3mm in diameter, in duplicate at least 2cm apart. Using a separate syringe and needle, inject a like amount of saline or allergen diluting solution as a control at least 5mm removed from the antigen test sites. Most skin reactions will develop within 5-15 minutes and response to the skin test is read at 20 minutes as follows:

- Negative response — no increase in size of original bleb and no greater reaction than the control site.

- Ambiguous response — wheal only slightly larger than initial injection bleb, with or without accompanying erythematous flare and slightly larger than the control site; OR discordance between duplicates.

- Positive response — itching and significant increase in size of original blebs to at least 5mm. Wheal may exceed 20 mm in diameter and exhibit pseudopods.

If the control site exhibits a wheal greater than 2-3 mm, repeat the test, and if the same reaction is observed, a physician experienced with allergy skin testing should be consulted.

HOW SUPPLIED: NDC 49471-001-05

PRE-PEN® (benzylpenicilloyl polylysine injection USP) is a clear, colorless, sterile solution supplied in ampules containing 0.25 mL.

Box of 5 single dose ampules. Ampules are opened by snapping the neck of the ampule using two forefingers of each hand. Visually inspect for glass shards before use. Each ampule is for single patient use only. Discard any unused portion.

PRE-PEN is optimally stored under refrigeration (2-8 C). PRE-PEN subjected to ambient temperatures for more than 24 hours should be discarded. As with all parenteral drug products, PRE-PEN should be inspected visually for particulate matter and discoloration prior to administration.

Rx only

Manufactured by AllerQuest LLC
10 Farmington Valley Drive, Suite 106, Plainville, CT 06062
Distributed by ALK-ABELLO, Inc
1700 Royston Lane, Round Rock, TX 78664
Printed in USA
DIRECTIONS FOR USE OF THERAPEUTIC ALLERGENIC EXTRACTS

WARNING

This product is intended for use by physicians who are experienced in the therapeutic use of allergenic extracts for the specific allergic condition of asthma, which is not life-threatening

Patients should be instructed to recognize adverse reaction symptoms and for any unusual symptoms following therapy be treated as if the patient were not previously treated. Under no circumstances should patients attempt to treat their own symptoms or the symptoms of others. Infections or local reactions should be treated as indicated in the "Warnings".

PRECAUTIONS

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7. Extracts in 50% glycerin can cause discomfort at the site of the injection.

PREGNANCY - CATEGORY C: Animal reproduction studies have not been conducted with allergenic extracts. It is also not known whether allergenic extracts can cause harm when administered to a pregnant woman or can affect reproduction capacity.

Controlled studies of hyposensitization with moderate to high doses of allergenic extracts during conception and all trimesters of pregnancy have not been conducted. Nevertheless, on the basis of histamine's known ability to contract the uterine muscle, the release of significant amounts of histamine from allergen exposure or hyposensitization protocols may result in uterine contractility.

PEDIATRIC USE: Children can receive the same dose as adults, however, to minimize the discomfort associated with dose volume it may be advisable to reduce the volume of the dose by one-half and administer the injection at a slower rate.

NURSING MOTHERS: It is not known if allergens administered subcutaneously appear in human milk. Because many extracts are derived from human milk, caution should be exercised when allergenic extracts are used to treat a patient during lactation.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY: Studies in animals have not been performed.

DRUG INTERACTIONS: Drugs can interfere with the performance of skin tests.

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Anaphylaxis and deaths following the injection of mite and other extracts have been reported. In some instances death has occurred 15 minutes after the injection. Anaphylaxis and deaths following the injection of mite and other extracts have been reported. In some instances death has occurred 15 minutes after the injection.

When diluting bulk extracts, use of Sterile Diluent for Allergenic Extracts or buffered saline is recommended. Dilutions should be made with sterile disposable syringes and needles. Potassium Phosphate, Citrate, Magnesium Phosphate and Calcium carbonate from glass media. These products are compounded and diluted on a w/v or PNU basis.

Intradermal skin testing at a dose 0.01 units AgE/mL. A series of 24 weekly injections were given subsequently with the usual skin test procedure to avoid the release of histamine in patients with a history of severe reactions to therapy. They are usually at their peak at 24 hours and can last for 72 hours. For a description and management of overdose reactions, refer to "Adverse Reaction" section above.

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The next therapeutic injection of extract should be reduced to the dose which did not elicit a reaction, and subsequent doses increased more slowly; i.e., use of intermediate dilutions.

Systemic: Systemic reactions are characterized by one or more of the following symptoms: Sneeze, mild to severe generalized urticaria, itching other than that associated with the disease, asthma, wheezing, dyspnea, cyanosis, tachycardia, laceration, marked perspiration, cough, stridor, chest pain, syncope and upper airway obstruction.

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Dosage and administration

Parenteral drug products should be inspected visually for particulate matter and macroscopic observations should be made before use. The incision should be made in a sterile manner, using aseptic technique. Commonly, 10fold dilutions are used to achieve a desired concentration for initiation and continuation of immunotherapy. For example, transferring 0.5 mL of a 10,000 PNU/mL extract into 4.5 mL of diluent.
Antigen E content and so labeled. The Antigen E content of extracts of pollens are individually extracted from pure pollen extracted in growth media.

Interval between doses in the early stages of immunotherapy is no more than once to twice a week, and may gradually be increased to once every two weeks.

Within 360 to 400 days after starting parenteral therapy, after completion of the ascending series of injections, INACTVATION may not elicit a response on testing. House Dust Extracts are among the most frequently encountered as a primary or accompanying allergen.

PERENNIAL TREATMENT

The patient’s tolerance to the offending pollen or pollens is first established by the injection of a series of graduated doses as outlined in the PRE-SEASONAL METHOD, not necessarily greater than once per day. Therapy may be begun at any time. After completion of the ascending series of injections, the degree of sensitivity that patients have to the allergens. For extracts derived from skin testing vs. the

determination of D5011. A general rule is to begin at 1/10 weight/volume ratio of 1:10 are obtained by calculating the Antigen E content based on the assay value of more concentrated extract.

DOSAGE ADJUSTMENTS

Adrenocorticosteroids may be administered parenterally or orally and plasma expanders may be required to reverse hypotension, inhalation bronchodilators and parenteral aminophylline may be required to reverse bronchospasm. In case of severe systemic reaction, short, cessation and inhalation may be necessary. Life-threatening reactions unresolved within 20 to 30 minutes after testing. Comparisons with whole pollen extract and placebo. J. Allergy Clin. Immunol. 42:93, 1968.

In transferring patients from unstandardized to standardized product, the physician should establish the potency relationships, perhaps by comparative skin testing and encouraged to report any

PREPARATION FOR PERIODIC TESTING

NOTE: For extracts of Short Ragweed or equal part mixture of Short and Tall Ragweed, the season, hay fever symptoms develop, relief may be provided by giving theophylline, oxygen, intubation and after

INFORMATION FOR PATIENTS:

GENERAL:

Patients should be instructed to describe any active allergic reactions resulting in respiratory obstruction, shock, coma and/or death. Adverse events are to be reported to MedWatch (1-800-FDA-1088). J. Allergy Clin. Immunol. 66:500, 1980.

Contraindications

Patients on beta blockers can be non-responsive to beta agonists that may be required to reverse a systemic allergic reaction (also, see boxed WARNING section). The physician should carefully weigh the benefit derived from skin testing vs. the risk to the patient should a systemic reaction arise.

To a fatal outcome from a systemic allergic reaction. The physician should carefully weigh the benefit derived from skin testing vs. the risk to the patient should a systemic reaction arise.

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Volume expanders and vasopressor agents may be required to reverse hypotension, inhalation bronchodilators and parenteral aminophylline may be required to reverse bronchospasm. In case of severe systemic reaction, short, cessation and inhalation may be necessary. Life-threatening reactions unresolved within 20 to 30 minutes after testing. Comparisons with whole pollen extract and placebo. J. Allergy Clin. Immunol. 42:93, 1968.

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and WARNING sections.

2. Store allergenic extracts between 2°-8°C at all times, even during use.

3. Care must be taken to avoid drawing blood.
   A. For percutaneous testing, if blood is observed, immediately wipe the allergen from the site.
   B. For intradermal skin testing, pull gently on the syringe plunger and note if any blood enters the syringe. If blood is observed, reposition the needle and repeat before injecting (see DOSAGE AND ADMINISTRATION).

4. Allergenic extracts become less potent with age. Allergenic extracts containing glycerin 50% v/v are relatively stable. Non-glycerinated aqueous extracts, particularly dilute forms as used for intradermal skin testing, have been shown to be extremely unstable. Until such time as stability studies are complete with dilute allergens, new intradermal strength materials should be prepared every five weeks.

5. Use standard aseptic precautions if making dilutions from stock concentrates to intradermal strength.

6. For intradermal testing: Extracts in glycerin 50% v/v must be diluted with a non-glycerinated diluent and must be diluted at least 25-fold to less than 2% glycerin by volume, as glycerin at this level can cause false positive intradermal skin test results.

Pregnancy - Category C: Animal reproduction studies have not been conducted with allergenic extracts. It is also not known whether allergenic extracts can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity.

Controlled studies of hyposensitization with moderate to high 25-fold to less than 2% glycerin by volume, as glycerin above this dilution may be unresponsive to bronchodilators and may require tracheal intubation and use of oxygen. In the event of a marked systemic reaction, an application of a cold pack above the injection site and the administration of 0.2 mL to 1.0 mL of epinephrine injection (1:1,000) is recommended. Maximum recommended dose for children between 2 and 12 years of age is 0.3 mL. The tourniquet should be left in place without loosening for 90 seconds every 15 minutes.

Adverse events should be reported via MedWatch (1-800-FDA-1088), Adverse Event Reporting, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852-9787.

OVERDOSAGE

Signs and symptoms of overdose are typically large local and systemic reactions, including manifestations of overdose reactions, refer to the ADVERSE REACTIONS section above.

DOSAGE AND ADMINISTRATION

Parenteral drug products should be inspected visually for particle matter and discoloration prior to administration, whenever solution and container permit.

Skin tests for immediate (Type I) hypersensitivity testing fall into three general categories: percutaneous, subcutaneous, and intradermal.

Percutaneous techniques: For percutaneous testing, in general, skin is scratched, punctured or pricked just before the allergen is applied or through a drop of test allergen. There are several devices available for this technique. Refer to the manufacturer or distributor’s circular for specific directions for their use.

In general:
1. It is recommended that the test areas should be placed no closer than 4 - 5 cm apart to avoid interference of reactions when several tests are applied.
2. Skin test areas should be cleansed with alcohol and air dried.
3. Preferably, the allergen should be placed on the volar surface of the forearm, upper arm, or the patient's back. The patient should be placed in a comfortable position prior to testing.
4. For scratch testing, a sharp, clean, sterile instrument is used to puncture the skin slightly, applying it at a 15 - 20° angle to the skin. The depth of the incision is generally raised, "testing" the skin just as it pops out, generally pricking through the drop of allergen. Do not draw blood.
5. For puncturing test, a sharp, clean, sterile instrument must be used. Puncture the skin, through the drop of allergen, perpendicular to the skin. Do not draw blood.
6. For all of the above techniques, a separate instrument must be used for each patient; if the instrument is to be used to pass through the allergen, to avoid cross-contamination, a separate instrument is to be used for each allergen. The test should be read in 15 minutes, measuring both wheal size and erythema.

Intracutaneous (intradermal) testing: General: Intradermal testing is more sensitive than percutaneous testing and its specificity is dependent on dose. Intradermal testing is not intended as an initial screen, but as a confirmatory test for the presence of positive or unclear history.


REFERENCES


Other drugs: Short acting steroids, inhaled beta2 agonists, theophylline and cromolyn do not seem to affect skin test response.

ADVERSE REACTIONS

Fatalties from skin testing in the United States have been extensively reviewed by Lockey.2 Six fatalities were associated with intradermal testing without previous percutaneous testing and one with intradermal testing with an intradermal "scratch" and intradermal skin testing. With careful attention to dosage and administration, fatal reactions occur infrequently, but it must be remembered that allergic reactions are highly potent to sensitive individuals and overdose could result in anaphylactic symptoms. Therefore it is imperative that physicians administering allergenic extracts for skin testing understanding, and be prepared for the treatment of severe anaphylaxis.

Local: Immediate wheal and erythema reactions are to be expected; but if very large, may be the first manifestation of a systemic reaction. In such cases, immediately wipe the test site(s) with sterile gauze or cotton to remove excess allergen.

2. Skin should be cleansed with alcohol and air dried.

3. A sterile 1 mL or 1/2 mL syringe with a 26 - 20 gauge needle should be used. A separate sterile syringe should be used for each extract and each patient.

4. Care should be taken to eliminate air bubbles from the syringe prior to injecting the test dose. It is suggested that not more than 6 - 10 allergens of different type be used at any one time. Very sensitive patients may show a positive response.

5. The skin is held tense, and the needle is inserted almost parallel to the skin, bevel side up far enough to cover the beveled portion. Slowly inject sufficient extract to make a small bleb of approximately 5 mm in diameter (0.01 - 0.02 mL).

6. Read the test results in 15 minutes.

Selection of the proper strength for intracutaneous testing: A generally accepted method of determination of units for reactions, particularly in extremely sensitive patients, is to screen by percutaneous methods initially, and begin intradermal testing at a strength not more than 1/100 of a negative or equivocal percutaneous reaction.

Controls: In both percutaneous and intracutaneous tests, a negative control test with diluent alone should be performed because some patients exhibit dermographia, and/or other non-specific irritant responses.

As a positive control in the evaluation of allergenic skin testing, histamine 0.1 mg/mL (histamine base) should be used for percutaneous testing, and histamine 0.1 mg/mL (histamine base) should be used for intradermal testing.

Interpretation of results: Patient's response is graded on the basis of the size of erythema or wheal.6 General guidelines follow for percutaneous reactions. Different types of tests influence the size of the reaction, therefore it is important to refer to the device manufacturer's or distributor's instructions when grading reactions.

Percutaneous (prick or scratch) test: 0 No reaction or less than control. + Erythema greater than control, smaller than a nickel (21 mm diameter). ++ Erythema greater than a nickel in diameter, no wheal. ++++ Wheal and erythema without pseudopods.**** Wheal and erythema with pseudopods.

Intradermal test: 0 No reaction or less than negative control. + 3-4 mm wheal with erythema, or erythema alone larger than a nickel (21 mm diameter). ++ 4-8 mm wheal and erythema, without pseudopods. ++++ Over 6 mm wheal and erythema without pseudopods.****+ Wheal and erythema with pseudopods.

HOW SUPPLIED

For scratch and prick testing: 5 mL dropper applicator vials in 50% v/v glycerin. Ky Fick, nickel sized, can be as long as 40 days (chlorapheniramine) as will as little as 24 hours (chlorpheniramine), and can be as long as 40 days (histamine) or up to 60 days (histamine) or up to 60 days.

For intracutaneous testing: 5 mL sterile vials, aqueous based, individually and in a complete set of the most common allergens. Available in either Protein Nitrogen Units (PNU/mL) or weight to volume (w/v).

Histatrol® Positive skin test control - histamine. 1 mg/mL and 0.1 mg/mL histamine base.

See Product Catalog for specific diagnostic concentrations available.

STORAGE

To maintain stability of allergenic extracts, proper storage conditions are essential. Bulk concentrates and diluted extracts are to be stored at 2° to 8°C even during use. Bulk or diluted extracts are not to be frozen. Do not use after the expiration date shown on the vial label.
For more information or to schedule an appointment to learn more, contact us at:

allergyinfo@alk.net 855.466.5482 addallergy.com