Penicillin Allergy Testing:
Purchasing & Ordering Guide

PRE-PEN®
(benzylpenicilloyl polylysine injection USP)
Skin Test Antigen

Visit **penallergytest.com** or contact us at **prepen@alk.net** to learn how ALK can help you impact antibiotic treatment through penicillin allergy skin testing.

Penicillin allergy is the **most commonly reported** drug allergy.[1]

10% of patients in the US—or **30 million Americans**—report penicillin allergy.[1]

9 out of 10 reporting a penicillin allergy are **not truly allergic.**[1]

80% **Up to 80%** of skin test positive patients **lose sensitivity** by 10 years.[2]

Why Penicillin Allergy Testing?

INCREASED EFFICIENCY
Overuse of broad-spectrum antibiotics leads to development and spread of multiple drug-resistant bacteria.[1]

IMPROVED PATIENT CARE
Having a label of antibiotic allergy can lead to withholding of guideline-recommended antimicrobial therapies.[1]

COST SAVINGS
The mean antibiotic cost for patients allergic to penicillin is 63% higher than for those not allergic to penicillin.[1]

PRE-PEN® is FDA-approved for the assessment of sensitization to penicillin (*benzylpenicillin or penicillin G*) in patients suspected to have a clinical penicillin hypersensitivity.

Supplies Needed for One Patient Test:

1. Single PRE-PEN® ampule 0.2cc
2. PenG dilution (10,000 u/mL) 0.2cc
3. Histamine (1.0 mg/mL) 0.1cc
4. Saline 0.2cc
5. (5) Skin testing devices
6. (4) Syringe labels
7. (4) Alcohol swabs
8. (1) Reaction guide
9. (1) Recording form
10. (4) syringes (detachable needles)
11. (7) detachable needles total

* **Optional Oral Challenge:**
An oral challenge, although optional, is recommended by the CDC.
This may be performed with 250mg of amoxicillin or other drug of choice.

Purchasing Matrix

Item	Description	NDC/UPC	ALK	Amerisource	Cardinal	McKesson	Diagnostic
PRE-PEN® *(benzylpenicilloyl polylysine injection USP)* **Skin Test Antigen (5 ampules)**	5 ampules x .25mL each (1 ampule used per test)	49471-001-05	1058481	10002772	4300927	2166528	skin test antigen
Histatrol Histamine *(histamine phosphate)* **1.0mg/mL 5mL DV**	5mL dropper vial Multi-use	0268-0247-05	1041220	10099823	1612761	1985357	positive control
Penicillin G 10,000 u/mL - *Obtain from pharmacy or order available brand*	Usually available in 5MU or 20MU vials	*Recommended strength for skin testing per NIH (or equivalent) is 10,000 units/mL*					skin test antigen
Normal Saline - *Obtain from pharmacy or order available brand*	Saline	N/A					negative control
Penicillin Skin Test Convenience Kit (5 Kits per Order)	Contains testing supplies only, no antigens	N/A	1059360	10153136	5324173	3559937	testing supplies
4 or 7, 25-28G Syringes (TB) - *for prepping testing solutions/intradermals*	*Follow hospital protocols to determine the number of syringes needed. The 3 syringes used for intradermals require needles.*						
DuoTip-Test® II Skin Test Device 20 Packs of 20 DuoTip	Qty: 400 tips total (5 tips used per test)	892093002050	1042815	10099767	4511549	3495285	skin test device
Alternative ordering option for DuoTip-Test® II	**Description**	**NDC/UPC**	**ALK**	**Amerisource**	**Cardinal**	**McKesson**	**Diagnostic**
DuoTip-Test® II Skin Test Device Box of 50 packs. 5 DuoTips/pack	1 pack needed per test	N/A	1058155	*Available via drop ship from ALK*			skin test device

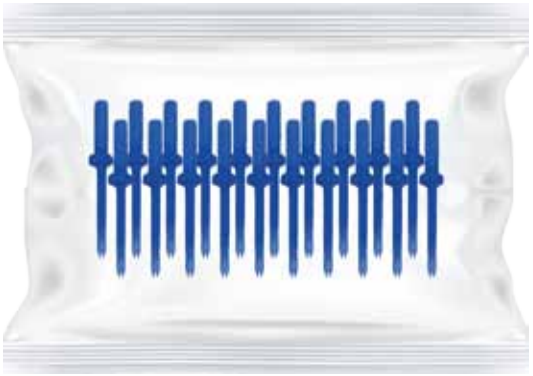
Penicillin Skin Testing Supply Kit

1. DuoTip-Test® II Devices (5-pack)
2. Pre-printed Syringe Labels
3. Alcohol Swabs
4. Reaction Guide
5. Skin Test Recording Form
6. Test Preparation Instruction Card

More Info on DuoTip-Test® II

DuoTip-Test® II is a sterile, disposable, plastic bifurcated needle used to administer skin test substances. When employed with allergenic extracts, it provides a quick, convenient and standardized procedure that is well-accepted by patients. Before using DuoTip-Test® II, or any testing device, the administrator must carefully study the package inserts accompanying allergenic extracts and control solutions.

Box of 400 (20 devices per unit container)



5-pack

CONTACT ALK FOR ADDITIONAL RESOURCES INCLUDING:

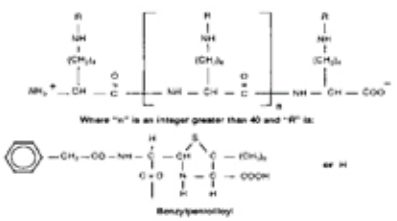
Onsite In-Service Training • Testing Demonstration Videos
On-demand Interactive eLearning Modules

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 penicilloyl groups (50-70%) forming penicilloyl alpha amide. Each single dose ampule contaiins 0.25 mL of PRE-PEN.

PRE-PEN has the following structure:



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 structural group which is a hapten. A hapten is a low molecular weight chemical that conjugates with a carrer (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 devleop 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 antibiodies which are necessary but not sufficient for acute allergic reactions due to the major penicilloyl determinant.

Non-benzylpenicilloyl haptens 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 significant clinical hypersensitivity. PRE-PEN does not react with IgE antibodies directed against non-benzylpenicilloyl haptens.

INDICATIONS AND USAGE:

PRE-PEN is indicated for the assessment of sensitization to penicillin (benzylpenicillin or penicillin 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 penicilin 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, puncture 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 administering therapeutic penicilling (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 weighted 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 treated a skin test antigen-induced reaction—the applications of a venuous occlusion tourniquet proximal to the skin test site and administration of epinephrine are recommended. The patient should be kept under observation for several hours.

DOSAGE AND ADMINISTRATION:

Skin Testing Dosage and Technique:

Skin testing responses can be attenuated by interfering drugs (e.g. H1-antihistamines and vasopressors). Skin testing should be delayed until the effects of such drugs have dissipated, or a separate skin test with histamine can be used to evaluate persistent antihistaminic effects in vivo. Due to the risk of potential systemic allergic reactions, skin testing should be performed in an appropriate healthcare setting under direct medical supervision.

Puncture Testing:

Skin testing is usually performed on the inner volar aspect of the forearm. The skin test antigen should always be applied first by the puncture technique. After preparing the skin surface, apply a small drop of PRE-PEN solution using a sterile 22-28 gauge needle. The same needle can then be used to make a single shallow puncture of the epidermis through the drop of PRE-PEN.

Very little pressure is required to break the epidermal continuity. Observe for the appearance of a wheal, erythema, and the occurance of itching at the test site during the succeeding 15 minutes at which time the solution over the puncture site is wiped off. A positive reaction consists of the development within 10 minutes of a pale wheal, sometimes with pseudopods, surrounding the puncture site and varying in diameter from 5 to 15 mm (or more). This wheal may be surrounded by a variable diameter of erythema, and accompanied by a variable degree of itching. The most sensitive individuals develop itching quickly, and the wheal and erythema are prompt in their appearance. As soon a positive response as defined above is clearly evident, the solution over the scratch should be immediately wiped off. If the puncture test is either negative or equivocally positive (less than 5mm wheal with litle or no erythema and no itching), an intradermal test may be performed.

The Intradermal Test:

Using a 0.5 to 1.0 cc syringe with a 3/8" to 5/8" long, 26 to 30 gauge, short bevel needle, withdraw the contents of the ampule. Prepare with an alcohol swab a skin test area on 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 system as a control at least 5cm 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 control site.

Ambiguous response—wheal only slightly larger than original 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 20mm in diameter and exhibit pseudopods.

If the control site exhibits a wheal greater than 2-3mm, repeat the test, and if 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

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