Penicillin Allergy Testing: Purchasing & Ordering Guide

PRE-PEN®
(benzylpeniciloxy 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.
**Supplies Needed for One Patient Test:**

1. Single PRE-PEN® ampule
2. PenG dilution (10,000 u/mL)
3. Histamine (1.0 mg/mL)
4. Saline
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

**Purchasing Matrix**

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>NDC/UPC</th>
<th>ALK</th>
<th>Amerisource</th>
<th>Cardinal</th>
<th>McKesson</th>
<th>Diagnostic</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRE-PEN® (benzylpenicilloyl polylysine injection USP) Skin Test Antigen (5 ampules)</td>
<td>5 ampules x .25mL each (1 ampule used per test)</td>
<td>49471-001-05</td>
<td>105841</td>
<td>10002772</td>
<td>4300927</td>
<td>2166528</td>
<td>skin test antigen</td>
</tr>
<tr>
<td>Histatrol Histamine (histamine phosphate) 1.0mg/mL 5mL DV</td>
<td>SML dropper vial Multi-use</td>
<td>0268-0247-05</td>
<td>1041220</td>
<td>10099823</td>
<td>1612761</td>
<td>1985333</td>
<td>positive control</td>
</tr>
<tr>
<td>Penicillin G 10,000 u/mL - Obtain from pharmacy or order available brand</td>
<td>Usually available in 5MU or 20MU vials</td>
<td>Recommended strength for skin testing per NIH (or equivalent) is 10,000 units/mL</td>
<td>skin test antigen</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal Saline - Obtain from pharmacy or order available brand</td>
<td>Saline</td>
<td>N/A</td>
<td>1059360</td>
<td>10153136</td>
<td>5324173</td>
<td>3559937</td>
<td>testing supplies</td>
</tr>
<tr>
<td>Penicillin Skin Test Convenience Kit (5 Kits per Order)</td>
<td>Contains testing supplies only, no antigens</td>
<td>N/A</td>
<td>1059360</td>
<td>10153136</td>
<td>5324173</td>
<td>3559937</td>
<td>testing supplies</td>
</tr>
<tr>
<td>4 or 7, 25-28G Syringes (TB) - for preparing testing solutions/intradermals</td>
<td>Follow hospital protocols to determine the number of syringes needed. The 3 syringes used for intradermals require needles.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DuoTip-Test® II Skin Test Device 20 Packs of 20 DuoTip</td>
<td>Qty: 400 tips total (5 tips used per test)</td>
<td>892093002050</td>
<td>1042815</td>
<td>10099767</td>
<td>4511549</td>
<td>3495285</td>
<td>skin test device</td>
</tr>
</tbody>
</table>

**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.
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 the corresponding protein which is produced by the fermentation of Penicillium chrysogenum. The derivatized polypeptide is a mixture of synthetic polypeptide chains containing benzylpenicilloyl oligomers and, specifically, 10 to 20 benzylpenicilloyl oligomers and 15 to 30 non-benzylpenicilloyl oligomers. Each single dose ampule contains 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 will also react to benzylpenicilloyl. This is the major penicillin-specific antigen. Therefore, individuals showing a positive reaction to benzylpenicilloyl will react to PRE-PEN. Individuals who react to benzylpenicilloyl do not necessarily react to benzylpenicilloyl polylysine. Rarely, a systemic allergic reaction (anaphylaxis) is not established. Similarly, when deciding whether to repeat the test, and if same reaction is observed, a systemic allergic reaction is not established. A systemic allergic reaction is not established. Anaphylaxis is not established. This can be used to make a single shallow puncture of the epidermis through the drop of PRE-PEN.

PRECAUTIONS:

General:
No reagent, test, or combination of tests will completely assess the risk of administering therapeutic penicillin (when penicillin is the preferred drug of choice) in the presence of clinical penicillin hypersensitivity. The benzylpenicilloyl hapten is the major allergenic 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 antibodies which are necessary but not sufficient for a systemic allergic reaction 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 significant 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 penicillin G) in patients suspected to have clinically significant penicillin allergy. 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, puncture skin testing should be performed first. Intradermal skin testing should be performed only if the puncture test is entirely negative.