Penicillin G: Reconstitution and dilution for penicillin allergy skin testing

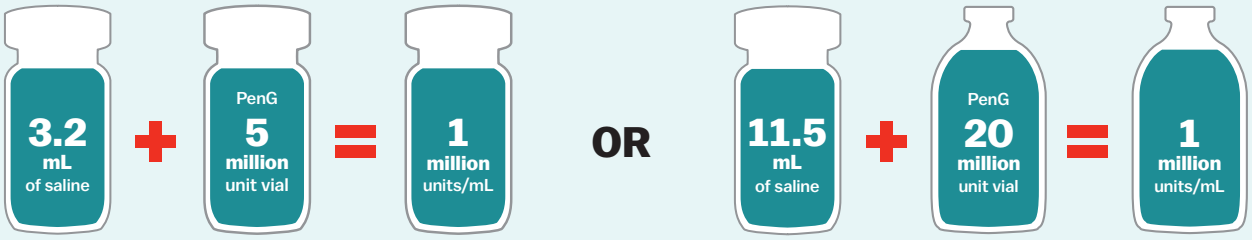
Prior to administering the test, penicillin G potassium or sodium must be reconstituted and diluted to a concentration of 10,000 units/mL

Before you begin the reconstitution and dilution process, you will need these supplies:

- One 1-5 cc syringe
- PenG powder
- Saline
- One ≥100-mL sterile empty vial (if using Step 2, Option A, for dilution) or 2 ≥10-mL sterile empty vials (if using Step 2, Option B, for dilution)

Step 1: Identification and reconstitution

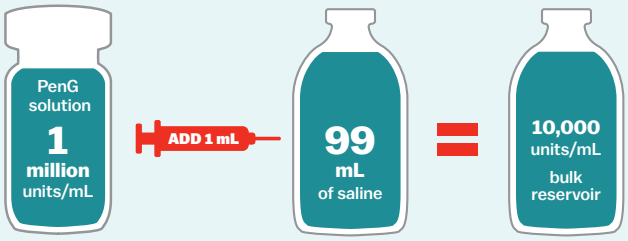
There are several penicillin G (PenG) products that can be used. Please follow the package labeling for your specific PenG product for reconstitution to a concentration of 1,000,000 units/mL



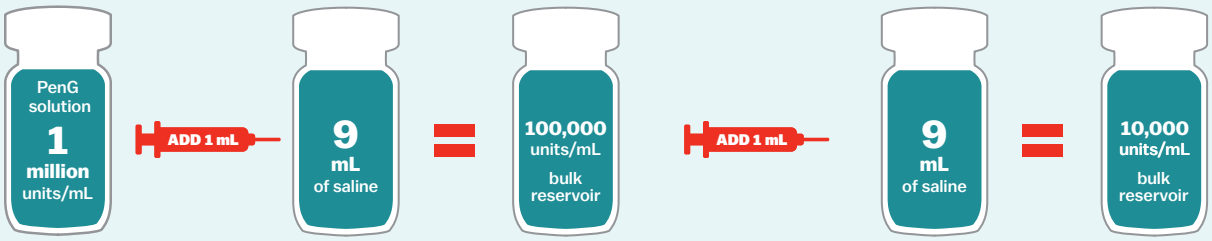
Step 2: Dilution options[1]

Once the vial contents have been reconstituted in Step 1, there are 2 ways to achieve the goal concentration of 10,000 units/mL

Option A



Option B



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

Please see Indication and Important Safety Information on reverse side and enclosed full Prescribing Information.

INDICATION

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 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.

IMPORTANT SAFETY INFORMATION

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.

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.

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 penicillin (when penicillin is the preferred drug of choice) in the following situations is not established:

- Adult patients who give no history of clinical penicillin hypersensitivity.
- 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 semisynthetic penicillins (phenoxymethylpenicillin, 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:

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

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.

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.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see enclosed full Prescribing Information.

Visit penallergytest.com to learn about the importance of penicillin allergy testing.

Reference: 1. Joint Task Force on Practice Parameters; American Academy of Allergy, Asthma and Immunology; American College of Allergy, Asthma and Immunology; Joint Council of Allergy, Asthma and Immunology. Drug allergy: an updated practice parameter. *Ann Allergy Asthma Immunol*. 2010;105(4):259-273. doi:10.1016/j.anai.2010.08.002

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