



NORTH TEXAS ALLERGY & ASTHMA ASSOCIATES

TEXAS HEALTH RESOURCES DALLAS

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PRE-PEN - PENICILLIN SKIN TESTING

What is PRE-PEN?

- PRE-PEN is the only FDA approved skin test for the diagnosis of penicillin allergy. PRE-PEN is administered through both scratch and intradermal testing, and quickly identifies patients who can safely receive penicillin.
- Allergy to penicillins and related antibiotics is the most commonly reported drug allergy in the United States. Approximately 85% of patients who describe themselves as penicillin allergic will have negative skin tests, and can safely receive penicillin and related antibiotics.
- Penicillin allergy is overstated due mostly to non-confirmed, self-reported patient history. Demonstrating the true presence of penicillin allergy with PRE-PEN can be a critical element in patient care.

Some potential benefits of PRE-PEN penicillin skin testing

- Unnecessary denial of an effective and well tolerated treatment
- Decreased out of pocket costs for antibiotics, since many alternatives to penicillins are costly
- Decrease the overuse of broad spectrum antibiotics which leads to increased drug-resistant bacteria

Some risks and contraindications of PRE-PEN penicillin skin testing

- Rarely, a systemic allergic reaction including anaphylaxis may follow a skin test with PRE-PEN. We take precautions to decrease the risk of a systemic allergic reaction by first performing skin testing.
- Patients known to be extremely hypersensitive to penicillin should not be tested. Also, those who have clear histories of severe skin reactions, such as Stevens-Johnson syndrome or toxic epidermal necrolysis, should not undergo penicillin skin testing, since such testing may reactivate their disease.
- **No reagent, test, or combination of tests will completely assure that a reaction to penicillin therapy will not occur.**

What is the procedure of the PRE-PEN penicillin skin testing?

- Please inform us of your past medical history, all current medications, as well as penicillin allergy history
- The actual PRE-PEN penicillin procedure involves applying prick skin tests with PRE-PEN in conjunction with Penicillin G, plus positive (histamine) and negative (diluent) controls. If the skin test is negative, we will then apply intradermal tests along with a control.
- Afterwards, we will examine the test sites for the appearance of a wheal and erythema. If the skin testing is negative, we may perform an oral challenge. You will be monitored in the office following the challenge for any reaction. The whole procedure takes about 2 hours.

Which patients are good candidates for penicillin skin testing?

- Any patient with a history of a reaction to a penicillin antibiotic that may have been IgE-mediated
- Any patient who is currently denied access to beta Lactam antibiotics out of concern for such reactions

What do I need to do before penicillin skin testing?

- Stop oral antihistamines and steroids for a week before testing, because these medicines will interfere with results
- Wear a short sleeve shirt, as the penicillin skin testing will be performed on your arms



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INFORMED CONSENT FOR PRE-PEN TESTING

I request North Texas Allergy & Asthma Associates to administer PRE-PEN testing for the diagnosis of a penicillin allergy. I will be completely forthcoming and detailed with my medical history, especially as it pertains to reactions with penicillin (and like substances). This is important because PRE-PEN is contraindicated in those patients who have exhibited a systemic or marked local reaction to a previous administration of penicillin (and like substances). I acknowledge that if I have been extremely hypersensitive to penicillin, that I should not be skin tested. By signing this consent, I also acknowledge the following:

PRE-PEN testing may be read falsely negative if I am taking interfering drugs (e.g. H1-antihistamines and vasopressors). PRE-PEN should be delayed for about 5 days until the effects of such drugs have dissipated. Also, if I have a history of severe skin reactions, such as Stevens-Johnson syndrome or toxic epidermal necrolysis, I should not undergo penicillin skin testing, since such testing may reactivate these diseases.

The clinical value of PRE-PEN skin tests alone in determining the risk of administering semisynthetic penicillins (phenoxymethyl penicillin, ampicillin, carbenicillin, dicloxacillin, methicillin, nafcillin, oxacillin, amoxicillin), cephalosporin derived antibiotics, and penem antibiotics is not known. **I also understand that no reagent, test, or combination of tests will completely assure that a reaction to penicillin therapy will not occur.**

PREGNANCY: It is not known whether PRE-PEN can cause fetal harm when administered to a pregnant woman, or if it can affect reproduction capacity. If I am pregnant, or could possibly be pregnant, I will postpone Pre-Pen testing.

ADVERSE REACTIONS: Rarely a systemic allergic reaction, including anaphylaxis, may follow a skin test with PRE-PEN. Precautions are taken to decrease the risk of a systemic allergic reaction by first performing skin testing. Occasionally, patients can develop an intense local inflammatory response at the skin test site, manifested by generalized erythema, pruritus, angioedema, urticaria, dyspnea, hypotension, and anaphylaxis. If this occurs, I consent for the staff at North Texas Allergy & Asthma Associates to treat these symptoms and I will stay in the clinic as deemed necessary by the staff. I (we) will notify the doctor or staff immediately if I (we) have any allergic reactions to my injections so that proper treatment can be initiated. I (we) understand that any time an injection is given; there is a rare chance of nicking a tiny blood vessel causing a bruise, numbness or pain. I (we) will notify the staff or physician if I have any problems at the site of injection.

If skin testing is negative, an oral challenge with penicillin may be used. I (we) understand that I am required to wait for at least 45 minutes after the oral challenge test. If I (we) leave early, or against the advise of the staff, I (we) understand that it is against medical advice and will hold my treating physician and North Texas Allergy & Asthma Associates and their staff free of any liability.

I (we) understand that I (we) should not use Beta-Blockers because of the inability to treat an allergic reaction, including hypotension or shock. I (we) also understand that while having Pre-Pen testing that I (we) should not use MAO Inhibitors drugs for depression unless specifically approved by my treating physician at North Texas Allergy & Asthma Associates, since such drugs may cause high blood pressure when adrenalin or other prescription medications are administered.

I (we) have been given the opportunity to ask questions about my condition and treatment, the procedures to be used, and the risks and hazards involved. Also I have had the opportunity to review the full prescribing information at prepen.com. I (we) believe that I (we) have sufficient information to give this informed consent. I (we) acknowledge that this disclosure and informed consent has been fully explained to me, that I (we) have read it or have had it read to me and I (we) understand its contents.

Date: _____

Contact Phone #: _____

Patient Signature: _____

If minor, Name of Legal Guardian: _____

Patient Name: _____

Signature of Legal Guardian: _____



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PENICILLIN SKIN TEST RECORDING FORM

Patient Name: _____

Date of birth: ___/___/___

History of penicillin or beta lactam allergy: _____

Last use of antihistamine (or other med affecting response to histamine): _____ days ago
Medication(s): _____

Skin Test Instructions:

- In quick sequence, apply prick skin tests with penicillin reagents plus positive and negative controls;
- If prick skin test is negative or equivocal, apply ID test (2-3mm blebs) in **duplicate** along with saline control;
- Read each test at 15-20 minutes after placement

TEST DATE	LOT #	PRODUCT	PRICK		ID#1		ID #2		Results (Pos/Neg/Equiv)
			Wheal	Flare	Wheal	Flare	Wheal	Flare	
		PrePen®[PPL] (undiluted)							
		Penicillin G (10,000 U/ml)							
		Diluent Control							
		Histamine (1.0 mg/ml)							

Criteria for positive prick skin test: Induration >3mm greater than diluent control

Criteria for positive intradermal skin test: Significant increase in size of original bleb with wheal diameter 3mm or more larger than diluent control; itching and flare are commonly present

Criteria for negative intradermal skin test: No increase in size of original bleb and no reaction greater than control site

Equivocal intradermal skin test: Wheal only slightly larger than initial injection bleb and control site, with or without erythematous flare OR duplicates are discordant.

Control site: If wheal >2-3mm after 20 min, repeat skin test to look for dermatographism

If skin test negative, Oral Challenge: _____ mg of _____ given

Reaction YES/NO If yes, describe: _____