Providence HEALTH CARE	**RESPIRATORY SERVICES**	DATE CREATED: May 2016 DATE REVIEWED/REVISED: **October 2016**
POLICY & PROCEDURE	TITLE: RESPIRATORY EDUCATION Centre: Allergy Testing: Skin Prick Test Respiratory Therapy NUMBER: B-00-12-12136	RELATED DOCUMENTS:

SITE APPLICABILITY:

ST. PAUL'S HOSPITAL

POLICY STATEMENT:

Allergy Testing using the skin prick method will be performed on adults in the Respiratory Education Centre by qualified respiratory therapists using standardized procedures and techniques in order to provide accurate test results in a safe testing environment. Testing will be done for common environmental allergens only (i.e. no foods). Testing should only be performed when physician support in case of adverse reaction is readily available. The physician will be responsible for the administration of any emergency medications (antihistamine, epinephrine, steroid) if required.

GENERAL INFORMATION:

Skin prick testing provides information about the presence of specific IgE to protein and peptide antigens (allergens). Small amounts of allergen are introduced into the epidermis and non-vascular superficial dermis, which may interact with specific IgE bound to cutaneous mast cells. Histamine and other mediators are then released, leading to a visible "wheal-and-flare" reaction peaking after about 15 minutes.

The value of this test depends on a number of variables, including:

- The relevance of the test allergen to the condition under investigation
- The correct introduction of a sufficient amount of allergen in its native (allergenic) form
- The functional status of cutaneous mast cells
- The interpretation of the reaction in the context of positive and negative controls

Correctly used, the skin prick test has good sensitivity and specificity for the presence of allergen-specific IgE, and is in some cases is more sensitive than *in-vitro* testing for specific IgE in serum. The discomfort is small and the risk of systemic reactions is minimal although not negligible.

Allergy testing has been shown to increase the accuracy of diagnosis when added to history and clinical examination, and it differentiates allergic diseases from other mimicking conditions. It may lead to allergy avoidance strategies, improved use of medications, and for some patients, desensitization treatment (immunotherapy). The strongest indication for skin prick testing is when there is good evidence for the effectiveness of allergen avoidance or immunotherapy.

Ultimately the integration of skin prick test results, knowledge of the biology of the various allergens and the exposures of the patient, and the nature and timing of the symptoms enable the construction of a diagnosis and appropriate management plan for the patient.

EXHIBITS:

A. Table 1. List of Allergens
B. Table 2. Product and Ordering Details
C. Appendix I. Allergy Testing: Patient Information Sheet – List of Medications to Withhold
D. Appendix II. Allergy Testing: Skin Prick Test Record Sheet
E. Appendix III. Allergy Testing: Skin Prick Test Quality Assurance Test Form

INDICATIONS:

- Rhinitis/rhinoconjunctivitis/rhinosinusitis/allergic conjunctivitis
- Asthma
- Atopic dermatitis

CONTRAINDICATIONS:

RELATIVE:

- Persistent severe/unstable asthma
- Pregnancy

ABSOLUTE:

- Diffuse dermatological conditions (test must be performed on normal health skin)
- Severe dermatographism* (skin testing should not proceed if dermatographia is present)
  **dermatographism (skin writing) is when the act of scratching the skin causes a wheal-and-flare reaction*
- Poor patient cooperation/compliance
- History of anaphylaxis to an allergen being tested
- Patient unable to hold taking antihistamines or other interfering drugs

NOTE: Beta-blockers are contraindicated in situations where the risk of systemic anaphylaxis is increased, as the beta-blockers interfere with the effect of epinephrine (see Special Considerations).

RISK FACTORS:

Risk factors for anaphylaxis in skin prick testing include:

- Non-commercial extracts
- Asthma, particularly if active or uncontrolled

ADVERSE EFFECTS:

Skin prick testing is an extremely safe procedure with minimal discomfort. Rarely, adverse events may occur; these can be classified into allergic, test-related non-allergic, and non-specific.

1. Examples of test-related non-allergic responses might include transmission of infection (theoretical but never documented).
2. Examples of non-specific responses are syncope and headache. Vasovagal syncope is relatively common, and for this reason, skin prick testing should be done in the seated position.
3. The expected reaction to a skin prick test is a localized wheal-and-flare. Delayed local skin swelling (late phase response) which is often tender or painful may occur uncommonly as a result of an IgE-mediated late-phase reaction (seen more commonly with intradermal testing). Rarely, this can cause quite marked swelling and discomfort, however it does not usually last more than 36 hours.
4. Systemic introduction of allergen may occur as an unintended consequence of the skin prick. Systemic reactions from skin prick testing may include:

- Anaphylaxis
- Generalized urticaria
- Angioedema, including airways angioedema, bronchospasm, and hypotension

NOTE: These reactions are generally mild and respond to standard treatment measures (antihistamines or epinephrine).

NOTE: There are many case reports of systemic allergic reactions from skin prick testing although in large case series this is exceedingly rare. In a survey of 16,000 individuals tested with eight routine allergens, the rate of adverse reactions was 0.04% and most of these were syncope, near-syncope or malaise. In another large survey, the rate of systemic allergic reactions was 0.044%, all occurring in asthmatics.

5. A small number of fatalities are reported as a result of *intradermal* skin tests but there is only one reported fatality from skin prick testing (however this was an atypical case and many of the risk factors mentioned were present).
6. Rarely, delayed systemic reactions in association with large late-phase responses have been reported. These usually consist of wheezing in asthmatic patients who had strongly positive skin prick tests commencing several hours after the test.
7. Due to the low risk of a systemic reaction occurring after the test has been completed, it is recommended that patients should remain in the waiting area for 10 minutes following the end of their test (totaling 30 minutes of observation from the time the last allergen is applied).
8. **If a patient has a reaction of 20 mm or more, obtain the emergency drug kit and consult with the physician regarding an order for the patient to take an antihistamine and/or steroid tablet prior to allowing them to leave. The physician will be responsible for the administration of the tablet(s) to the patient.**
9. **If a severe response or anaphylactic reaction occurs, notify the physician and obtain epinephrine from the emergency drug kit. The physician will be responsible for the administration of the epinephrine to the patient.**

CAUTIONS:

In cases of severe dermatographism, a nonspecific wheal-and-flare can result from the act of skin pricking alone. The negative control may show a wheal and this renders the allergens difficult to interpret unless the reaction is markedly larger than the negative control (see Procedure Notes and Method Limitations). Mild dermatographism does not preclude skin testing.

The following factors may lead to some variability, but is not usually significant in result interpretation:

- Menstrual phase
- Race
- Circadian rhythm
- Seasonal variation
- Atopic dermatitis (elsewhere on the body)

The following conditions can reduce skin test reactivity:

- Chronic renal failure
- Certain cancers
- Spinal cord injury
- Diabetic neuropathy
- Recent anaphylaxis

Skin prick testing should not be carried out on limbs affected by lymphedema, paralysis or neurogenic abnormalities.

SPECIAL CONSIDERATIONS:

1. Precautions must be taken to prevent bacterial contamination and cross-contamination between allergens. The following practical measures should be used:
   - Place the test solutions in order in the rack
   - Check each bottle label before opening
   - Only open one bottle at a time (if a dropper is put into the wrong bottle, this results in contamination with the other allergen, and bottle and dropper must be discarded)

- Clean the patient's skin prior to testing to prevent contamination of the tip of the dropper; use only on intact skin
- When depositing the allergen solution drop on the patient's skin, it is acceptable to touch the drop against the skin but not the tip of the dropper

2. Lancets should be discarded in the yellow sharps container after use.
3. Gloves should be worn throughout the procedure.
4. In the case of exposure to blood or body fluids (as in the instance of a sharps injury) and for details on emergency procedures, refer to the OH&S section of PHC Connect.

REQUIRED SUPPLIES & EQUIPMENT:

- Test sheet
- Allergen extracts
- Positive and negative control solutions
- Alcohol swabs
- Tissues
- Latex-free disposable gloves
- Lancets
- Pen
- Sharps container
- Ruler and calipers
- Emergency drug kit (epinephrine, diphenhydramine, dexamethasone)*
  *physician responsibility to administer

TABLE 1. List of Allergens

No.	ALLERGEN	COMMENTS
1	Positive control solution	Histamine Base 1mg/mL
2	Negative control solution	Glycerinated phenol – saline
3	Dog	Dog epithelium (1:20W/V)
4	Cat	Standardized cat pelt (100,000 BAU/mL)
5	Aspergillus mix	Four equal parts of *Oryzae, Repens, Niger, Terreus* (type of fungi that can grow in the lungs) 1:10 W/V
6	Standard Dust Mite Mix	5,000 AU each : *D. Pteronyssinus, D. Farinae*
7	Feathers	Contains 3 equal parts: Chicken, Duck, Goose
8	Pacific Grasses	Mixture of standard grass pollen
9	Trees Mix	Contains equal parts: Alder, Ash, Elm, Birch, Maple, Oak, Poplar, Sycamore 1:20 W/V
10	Black Willow	Black Willow 1:20 W/V
11	4 Weeds Mix	Contains 4 equal parts: Cocklebur, English Plantain, Pigweed, Lamb's Quarter
12	Sorrel/Dock Mix	Contains 2 equal parts: Sheep Sorrel, Yellow Dock

TABLE 2. Product and Order Details

ITEM NAME	VENDOR/SOURCE	PRODUCT NUMBER	PEOPLESOFT ID

PRE-PROCEDURE CONSIDERATIONS:

A. EQUIPMENT:

1. Gather all required equipment before beginning test.
2. Remove allergen solutions from refrigerator immediately before the beginning of the test, and return to the refrigerator as soon as possible following the procedure.
3. Check the expiry dates of the solutions prior to beginning testing.

B. PATIENT:

1. Must not have used antihistamines or other interfering drugs, or have applied skin moisturizers or perfumes prior to the procedure (see Appendix I).

C. ENVIRONMENT:

1. Testing room should be private and at a comfortable temperature, especially if the patient needs to partially disrobe in order to expose their forearms.
2. Magazines should be available for the 15 minutes required for the test to develop (to distract them from any discomfort).

D. ASSESSMENT OF PATIENT:

1. Confirm compliance with test preparation instructions (i.e. withholding of antihistamines and other interfering drugs, and no use of skin moisturizer or perfume). Check for any contraindications.
2. Explain the test to the patient and obtain verbal consent.
3. Ensure patient is seated in a comfortable position and have them remove any bracelets or watches.
4. Expose forearms and ensure there is no risk of clothing brushing across the test area.
5. Select the site of application:
   a. The preferred site is the volar surface of the forearm.
   b. Reactions to allergen (but not histamine) are larger on average on the back than the arm, larger on the lower than the upper back, and on the upper forearm compared to the wrist.
   c. Generally it is advisable to site tests more than 5 cm from the wrist and 3 cm from the antecubital fossa.
6. Ask the patient to gently scratch a small section of their skin to check for dermatographism.
7. Clean the test site with alcohol prior to skin testing (this may be contraindicated in cases of extreme dry skin and eczematous tendency).
8. Check the patient's arm for obvious dermatitis, scarring, tattoos or veins. These sites should be avoided.

TESTING PROCEDURE:

1. Draw marks on the patient's skin and number them. The prick tests should be at least 2 cm apart to avoid overlapping reactions and false-positive results.
2. Allergens will be applied from the dropper bottle prior to pricking the skin. The drop on the tip of the dropper can be touched on the skin to transfer the liquid but the actual tip of the dropper should not touch the skin.
3. In cooperative patients, or if a small number of allergens are used, all drops can be deposited before commencing pricking. In other cases it may be preferable to deposit a group of drops and prick them, then another group.
4. Place the drops beside the pen marks in a manner that will allow you to easily correspond with each allergen on the record sheet.
5. It is important not to allow the extract to run onto the next prick site.
6. In patients with eczema who use moisturizers the drop may flatten or run more easily on the skin.
7. Open a sterile lancet and prick the skin by passing the lancet through the allergen droplet (at a 90 degree angle to the skin) and applying gentle pressure.
   a. The lancet should pierce the top layer of skin.
   b. Pressure should not be hard enough to draw blood (although this may be difficult in elderly patients with thin skin).
   c. Pressure should be a consistent as possible for all pricks.
8. Between each prick, gently wipe the needle on an alcohol wipe (one lancet per 10 allergens). Always wipe the needle on the alcohol wipe and NOT vice versa – this method minimizes risk of sharps injuries.
9. After applying each set of allergens carefully remove the allergens from the skin by patting with a tissue.

Care must be taken not to cross-contaminate the solutions.

10. Some patients experience considerable discomfort as a result of the itching of the skin test. Explain that scratching can exacerbate the itch and affect the test results.

POST-TEST PROCEDURES:

A. RECORDING TEST RESULTS:

1. Results should be recorded after 15 minutes. The measurement of the wheals is time sensitive so there should be no delay in recording the results.
   a. The reaction to the histamine positive control is at its maximum size at approximately 10 minutes whereas the allergen reaction reaches its maximum at around 15 minutes
   b. In practice the histamine wheal is usually still showing at 15 minutes and this is recommended as the optimal time for reading skin test results.
   c. Occasionally, allergen responses continue to enlarge up to about 20 minutes. Overall, the histamine result should be read at 10-15 minutes after the skin prick and the allergens at 15-20 minutes after.
   d. If the test is left for longer than 20 minutes the histamine and allergen response may diminish or be lost and the test may need to be repeated.
2. Measure the mean diameter of the wheal, using the skin prick testing calipers or brass calipers (wiped with Cavi-wipes between patients).
3. Results should be recorded in millimeters on the Skin Prick Test Record Sheet (see Appendix II).
4. There are several common shapes of wheal that may occur as a result of the skin test:
   a. Circular:
      - Round in shape
      - Make one measurement of the mean diameter and record in mm
   b. Pseudopod:
      - Ovoid in shape, or has a 'tail'
      - Should be measured on the longest and shortest perpendicular axis and both numbers recorded (i.e. 3 x 6 mm)
      - May be considered a more significant allergic response and its presence should be noted in the test comments
   c. Satellite:
      - Multiple 'tails' on the wheal
      - The longest and shortest perpendicular axis should be measured and both numbers recorded, in addition, the mean central wheal diameter should be recorded
      - May be considered a more significant allergic response than a pseudopod and its presence should be noted in test comments
   d. Diffuse:
      - A wheal is observed at the puncture site, and one or more additional wheals are observed in the vicinity of the puncture site
      - Record the mean diameter of the wheal at the puncture site
      - The diffuse response should be noted in test comments
5. At the end of the test, pen marks should be removed from the skin using an alcohol swab (unless contraindicated by dry skin or a skin condition).

B. INTERPRETING AND PRINTING TEST RESULTS:

1. The clinic allergist interprets the results of skin prick tests. After documenting all of the results on the test record sheet, the results are given to the interpreting physician for interpretation.
2. The result of a skin prick test may have significant ramifications to the patient's lifestyle, diet, or occupation, and may determine prolonged courses of treatment and/or expensive environmental modification measures.
3. Skin prick test results need to be interpreted in the context of the patients' history, clinical signs, and allergen exposures. In the presence of a history of an allergic condition with a positive skin prick test and known exposure to the allergen, particularly when the pattern of symptom exacerbation relates to variations in allergen exposure it is reasonable to conclude that the allergen is relevant to the symptoms, and the positive test is significant.
4. The decision of whether a patient is truly allergic to the substance in question depends on careful interpretation of the skin prick test result as well as consideration of other clinical factors.
5. After being interpreted, the final copy of the results should be scanned and a copy printed for the patient record.

PROCEDURE NOTES AND METHOD LIMITATIONS:

1. The use of positive and negative controls are essential for the following reasons:
   a. Some patients develop a small flare or wheal from the pinprick alone. This leads to an apparent reaction to extracts to which the patient is not actually sensitized. The negative control would be expected to show a similar reaction. If this occurs then either the test must be rejected as uninterpretable (if there is insufficient distinction between the reaction to the negative control and the positive control), or interpreted by comparison with reaction to the negative control (i.e. if the negative control produces a wheal of 3 mm, only wheals of greater than 6 mm will be considered positive). Caution is required since the dermatographic response if often inconsistent at different skin sites, and may produce different reactions for a range of extracts to which the patient is not allergic. Wheals of greater than 3 mm to the negative control indicate severe dermatographism and would require rejection of the test. Careful technique can minimize nonspecific reaction in dermatographic patients.
   b. The positive control should produce a wheal of approximately 6 mm, and if there is no wheal or only a tiny one, this may indicate either that the patient has taken an antihistamine or a drug with antihistamine activity (see Appendix I) or that they have non-reactive skin, in which case a skin prick test will not be possible.
   c. It is recommended that a wheal of greater than 4 mm to the positive control is acceptable (or 4 mm greater than the negative control) and if less than 4 mm the test should be considered uninterpretable.
   d. The negative control is the same solution as the allergens are made up in (saline buffer/50% glycerol), and the positive control is a histamine solution and directly induces cutaneous wheal and flare response.
2. A wheal of 3 mm or greater is taken to indicate the presence of specific IgE to the allergen tested. The 3 mm lower cutoff was determined because of reproducibility of measurement rather than clinical relevance.
3. When properly conducted, the skin prick test is a highly sensitive and specific test for the presence of allergen-specific IgE antibody. However, the presence of IgE antibody (as defined by a positive skin prick test) does not prove that the patient is clinically reactive to the allergen.
4. Positive tests (sometimes even with large wheal size) may occur without clinical symptoms. The test result indicates that IgE is present, therefore the test is technically positive, but symptoms may not occur on exposure to that allergen. This may be referred to as “clinically silent sensitization”, or a “clinical false positive” test result (this individual may still be classified as atopic).
5. The size of the skin prick test reaction may correlate with the likelihood that the patient is clinically reactive to that allergen. For example, in groups of patients, a subgroup with larger wheal size will contain a higher proportion of individuals who react to the allergen upon challenge than a subgroup with smaller wheal size.
6. A positive skin prick test does not predict the nature of the allergic symptoms; different individuals with a positive test to the same substance may react in very different ways on exposure to the allergen.
7. Positive allergy tests may indicate a clinically true allergy but may be irrelevant (i.e. the patient is sensitized and clinically reactive but not exposed to that allergen, hence it is not the cause of their symptoms).
8. Skin prick tests may be positive when a patient has a previous history of allergy that has since resolved; for example, hay fever may remit in adults but pollen skin tests often remain positive.
9. Negative skin prick test results can occur even in the presence of true IgE-mediated allergy, due to inadequate representation of allergenic proteins in certain extracts.
10. Real false positive and false negative tests occur occasionally in clinical practice, often due to technical or human error. Real false positive or false negative tests are defined by being non-reproducible in the same individual.

DOCUMENTATION:

Documentation will be done on the Skin Prick Test Record Sheet (see Appendix II).

QUALITY ASSURANCE:

To ensure test proficiency, each practitioner should complete the following practical efficiency test prior to testing patients, and annually thereafter:

1. A skin test should be performed on a volunteer comprising 5 separate drops of negative control solution and 5 separate drops of positive control solution.

2. There should be no response measured from the negative control solutions.
3. The therapist should draw around the outer rim of the histamine wheals, place some tape over the drawing and transfer the drawing onto the tape.
4. Place the tape on a Skin Prick Test Quality Assurance Test Form (see Appendix III), and mean wheal size should be analyzed.
5. Co-efficient of variation should be less than 15% to ensure the therapist has a consistent pressure when applying the solutions.
6. The interpreting physician should then review the QA test results and will sign off the QA form if the proficiency test is acceptable.

REFERENCES:

1. Australasian Society of Clinical Immunology and Allergy Inc.: Skin Prick Testing for Diagnosis of Allergic Disease – A Manual for practitioners (revised March 2009).
2. The Lung Centre. VGH. Allergy Skin Testing Procedure Manual. Sept 2015.

DEVELOPED BY:

1. Adapted from the Australasian Society of Clinical Immunology and Allergy Inc.'s *Skin Prick Testing for Diagnosis of Allergic Disease – A Manual for Practitioners.*

REVIEWED BY:

1. Practice Leader, Respiratory Therapy
2. Respiratory Patient Educator, Respiratory Education Centre, Respiratory Services
3. Pulmonary Diagnostics Coordinator, Respiratory Services
4. Clinical Coordinator, Respiratory Services

APPENDIX I. Allergy Testing: Patient Information Sheet

RESPIRATORY SERVICES
RESPIRATORY EDUCATION CENTRE
ALLERGY TESTING: Skin Prick Test Patient Information Sheet

☐ Please **CALL** our Office at **604-806-8808 TWO WEEKS** before your scheduled appointment to confirm.

☐ **AVOID** taking **Allegra, Reactine, Claritin, Areus** during the **2 WEEKS** leading up your appointment.

- *If you normally take any of the medications on a daily basis and cannot stop them for two weeks, please stop taking them for a minimum of **3 days** before your appointment*

☐ **AVOID** taking all other **antihistamines** including **cold and sinus medications** during the **2 DAYS** before your appointment.

☐ It is okay to **CONTINUE USING** any of these medications as directed by your doctor:

- Asthma medications
- Anti-inflammatory medications
- Analgesics
- Nasal Sprays

If you are unable to keep the appointment made for you, please contact our Office as soon as possible at 604-806-8808.

APPENDIX II. Allergy Testing: Skin Prick Test Record Sheet

RESPIRATORY SERVICES
RESPIRATORY EDUCATION CENTRE
Allergy Testing: Skin Prick Test Record Sheet

Date: _____

Patient Name: _____

Referring physician: _____

Antihistamines taken prior to testing: YES / NO

If yes, name and date/time taken: _____

Respiratory medication: _____

ANTIGEN	WHEAL SCORE	ANTIGEN	WHEAL SCORE
Negative Control (Saline)		**Mold Mix**	
Cat Epithelium		**Grass Mix**	
Dog Epithelium		**Western Tree Mix**	
Feather Mix		**Weed Mix**	
House dust mite		**Positive Control (Histamine)**	

WHEAL SCORE *(after 20 minutes)*:

- 1-2 mm: 1+
- 3-5 mm: 2+
- 6-8 mm: 3+
- Greater than 9 mm: 4+

EDUCATION:

☐ Disease Pathophysiology
☐ Action Plan
☐ Medication Side Effects
☐ Trigger/Allergen Avoidance
☐ Smoking Cessation
☐ Treatment Review (anti-inflammatory vs. bronchodilator use)
☐ Medication list and instructions
☐ Warning Signs & Symptoms
☐ PEFrate and Symptom Monitoring
☐ Review/Educate Inhaler Technique *(indicate device):*
☐ MDI ☐ MDI + Spacer ☐ Handihaler ☐ Turbuhaler ☐ Diskus

COMMENTS:

_____
_____
_____

TESTED BY: _____, **RRT :** _____

APPENDIX III. Allergy Testing: Skin Prick Test Quality Assurance Test Form

RESPIRATORY SERVICES
RESPIRATORY EDUCATION CENTRE
Allergy Testing: Skin Prick Test Quality Assurance Test Form

DATE: _____

THERAPIST: _____

REVIEWER: _____

Performed on volar surface of: RIGHT / LEFT **arm**

ANTIGEN	WHEAL SCORE/TAPE	ANTIGEN	WHEAL SCORE/TAPE
Negative Control (Saline) #1		Positive Control (Histamine) #1	
Negative Control (Saline) #2		Positive Control (Histamine) #2	
Negative Control (Saline) #3		Positive Control (Histamine) #3	
Negative Control (Saline) #4		Positive Control (Histamine) #4	
Negative Control (Saline) #5		Positive Control (Histamine) #5	

WHEAL SCORE *(after 20 minutes)*:

- 1-2 mm: 1+
- 3-5 mm: 2+
- 6-8 mm: 3+
- Greater than 9 mm: 4+

COMMENTS:

_____

_____

_____

_____

_____

_____

PROFICIENCY ACCEPTABLE: YES / NO **FURTHER TESTING REQUIRED:** YES / NO

REVIEWED BY: _____