



CONSENT TO PARTICIPATE

DELAYED HYPERSENSITIVITY PATCH TEST

Patch tests are the standard for diagnosing allergic contact dermatitis. Based on your health history and consultation by _____, it has been determined that you may have allergic contact dermatitis and patch testing is recommended. The skin patch test will be administered using a procedure that is routinely used by dermatologists and allergists to assess delayed hypersensitivity. The chemical allergens are commercially available for this specific type of patch test skin screening. A series of standard chemical allergens will be applied to your back. To ensure that the allergens fully contact your skin, the back will not be cleansed prior to patch application, however, a hairy back may be lightly shaved (without the use of soaps or lotions).

Applying the patch will take approximately ten minutes. Patients should return to the designated areas as per the attached schedule after 48 hours to have the patch test removed. You will return to the designated site after 72 hours and/or 96 hours to have the patch tests read. Patients should leave the patch in a dry and well-adhered fashion until the patch test is read. As a patient, you will receive a written copy of the results upon completion of the patch test assessment. The benefit to you will be the information gathered regarding your responses to the patch test allergens which may help you manage your contact dermatitis.

During the entire duration of the patch test (96 hours), it is very important that you stay in cool environments and avoid vigorous work or activities to minimize sweating. In addition, you should not take showers to avoid wetting the back. However, you can take sponge baths. Once the patches are removed from your back at 48 hours, you may resume showering provided you refrain from direct water contact with the back or scrubbing, which may remove the orientation marks on your back that facilitate the readings at 72- and/or 96-hours.

Medications such as steroids (prednisone, prednisolone, Medrol Dosepak and steroid injections), topical steroid creams and chemotherapy for cancer can interfere with the patch test results and can cause false negative results. Please inform _____ if you have taken any of these medications in the preceding 4 weeks. Antihistamines such as Benadryl, Claritin, Zyrtec or Allegra do not interfere with patch testing and therefore can be continued.

Patch testing to antigens at standard concentrations and in standard vehicles is an extremely safe procedure. Most patients experience moderate discomfort such as itching and burning as a result of a reaction to one or more of the allergens, patch test panel or reinforcement tape used to keep the patch test in place on your back. Complications include flare-ups of contact dermatitis. Severe reactions (allergic or irritant) are rare but can lead to blistering, necrosis, scarring, keloids and light or dark pigmentation of the skin at the test site. Occasionally, persistent reactions or bacterial or viral infections may occur. An anaphylactic reaction may occur to antigens that are responsible for contact urticarial responses. Very rarely, patients are sensitized to an antigen by patch testing.

It is normal to experience some level of itching and/or irritation during patch testing, however, if you experience significant itching, irritation or pain at the site, you should contact us immediately. _____ will discuss the situation with you and advise you as to the best course of action for your comfort and safety. The patch tests have 70% sensitivity and specificity. This means a negative test does not rule out allergic contact dermatitis. If you have a positive test, then you should find out the relevance of the test by strictly eliminating all skin and body care products and other products containing the offending chemicals and see if the rash resolves over time.

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I have carefully read this Consent and understand its contents, and I have had the opportunity to ask any questions that I had about the study. **My participation is voluntary; I am under no obligation to participate in Patch Testing.** My refusal to participate will involve no penalty or loss of benefits to which I am otherwise entitled, and I may discontinue participation at any time without penalty or loss of benefits to which I am otherwise entitled. By signing this Consent, I authorize _____ to collect and disclose health information about me through subsequent educational or promotional vehicles (videos, manuscripts, brochures, advertisements, case report forms, etc.) *If I discontinue participation, _____ may continue to use and disclose the information gathered about me before my discontinuation as described in this consent form.*

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By signing below, I indicate that I agree to be patch tested as a patient of _____.

Printed Name: _____

Signature: _____

Date: _____