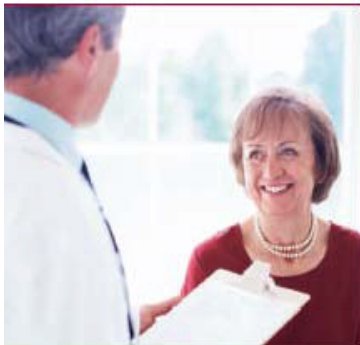


## APPLICATION OF T.R.U.E. TEST® (ALLERGEN PATCH TEST)

### PRETEST CONSIDERATIONS



**Assess all potentially relevant symptoms:** As with other clinical tests, the presence of clinically relevant symptoms and a positive health or occupational history increases the predictive value of patch test results and lowers the possibility of diagnostic errors. Patients should be asked to collect information about potential allergen contact at work and at home.

**Counsel patients about the nature, goals and limits of patch testing:** Optimal patch testing requires patient understanding, cooperation and commitment. Be aware of the impact of a patient's educational level and familiarity with medical terms. Also consider potential language barriers and cultural differences when counseling patients.

Explain to patients that patch testing is not like skin prick testing, or other allergy tests. Inform patients that negative as well as positive test results are common, and that both have value in resolving their dermatitis. Provide patients with a copy of “*Questions and Answers About T.R.U.E. TEST*” (see *Patient Information about T.R.U.E. TEST and Contact Allergens* section).

#### Important points to discuss with patients:

- What to expect from the testing process
- Multiple visits are required
- Loose clothing should be worn during the testing
- Test sites may be itchy and uncomfortable
- Oral corticosteroid medications need to be stopped temporarily
- No showering (sponge baths only) because T.R.U.E. TEST must be kept dry
- Vigorous exercise must be avoided and other activities may be limited
- A flare-up of dermatitis elsewhere on their body may occur
- Patients should contact their doctor if reactions become severe

**Determine the optimal date to begin testing a patient:** In patients with significant ongoing dermatitis, it is advisable to defer patch testing with T.R.U.E. TEST until symptoms are no longer severe. Patch testing during active outbreaks of dermatitis can result in excited skin syndrome and false positive results.

Discontinue immunomodulator and immunosuppressor therapy if possible. The biologic half-life of these drugs varies, and can range from less than 8 to over 50 hours. Therefore, it can take several days or weeks for their immunosuppressive effects to abate. For optimal test results, patients should avoid these drugs for 2 weeks prior to testing.

Topical therapies may be continued on non-test sites during patch testing. Patients may also continue to use over-the-counter skin and body lotions on non-test sites as they would normally.

Coordinate with patient schedules taking into consideration significant events, holidays, and weekend activities. This approach is more likely to encourage patient participation and a commitment to return for necessary second and third readings. Flexibility and creativity may be key for some patients with scheduling conflicts. For example, family members may be able to document skin reactions using digital photography, if the physician provides guidance and oversight.

**Select an appropriate test site:** Verify that an available patch test site on the upper back is free of significant scarring, skin disease and tanning. The recommended T.R.U.E. TEST application site is the upper back. Limited studies have indicated that skin responsiveness on the upper back may be greater due to an increased density of Langerhans cells and differences in the stratum corneum.

Alternative sites include the upper arm or other areas on the back that are not obstructed by clothing or affected by normal body movements. Regardless, skin at the selected site must be free from topical steroids, active dermatitis, skin damage, and signs of sunburn or significant tanning.



## PATIENT HISTORY INCLUDING ALLERGIES AND EXPOSURES

Detailed health and occupational histories help to identify risk factors (e.g., atopy), and possible sources and exposure routes of allergens and irritants at work and at home (see Patient History Form, Section 5).

**Using the *Patient Dermatology and Allergy History* form as a guide, ask for detailed information about:**

- Patterns of symptom eruption and distribution
- Family and personal history of allergies
- Pre-existing medical conditions
- Materials, products and pets encountered at home or during recreational activities
- Personal care products used
- Materials and products regularly encountered at work
- History of employment and related materials or products
- Relevant material safety data sheets (MSDS), product inserts and labels

Patients with symptoms consistent with allergic contact dermatitis should be advised to collect product content information from work and home to help identify potential allergens. Product content information can be obtained from material safety data sheets (MSDS), technical specifications, product inserts, and product labels.

**Clarify anatomical and time-dependent relationships between potential allergen exposure and symptom development. Be sure to ask patients about:**

- *When* symptoms appear, worsen and improve;
- *How long* symptoms last – i.e. hours, days or weeks;
- *Where* symptoms occur, e.g. hands, feet or elsewhere; and
- *What* activity was performed and using what products.

## T.R.U.E. TEST PANEL APPLICATION

The ready-to-use T.R.U.E. TEST panels should be applied to clean, healthy skin on the patient's upper back or outer surface of the arm. No mixing, measuring or advance preparation is required.

Cleansing of the test area is generally not necessary and should be avoided to minimize skin irritation. For similar reasons, use electric clippers or shavers to remove any unwanted body hair. Avoid using straight-edge razors that can irritate skin.



**STEP 1.** Peel open the package and remove T.R.U.E. TEST Panel 1.1.



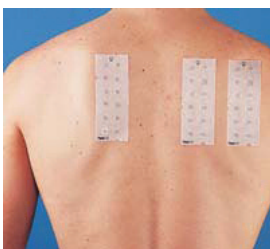
**STEP 2.** Carefully remove the protective cover from the test surface of the panel. Do not touch the test substances.



**STEP 3.** Position T.R.U.E. TEST Panel 1.1 on the upper left side of the patient's back (approximately 5 cm from the midline) so that the No. 1 allergen is in the upper left corner. Avoid applying the panel on the margin of the scapula. From the center of the panel, smooth outward toward the edges, making sure that each allergen contacts the skin firmly and completely.



**STEP 4.** With a surgical skin marker, mark the location of the panel's two notches on the skin. (A fluorescent skin marker can also be used to mark the panel notches and detected later using a Wood's lamp.)

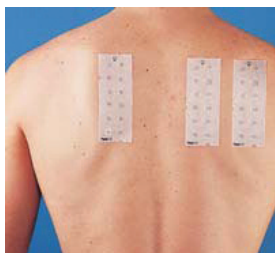


**STEP 5.** Repeat the process with T.R.U.E. TEST Panel 2.1. Position this panel on the upper right side of the patient's back so that the No. 13 allergen is in the upper left corner.

**STEP 6.** Repeat the process with T.R.U.E. Test Panel 3.1, with No. 25 allergen in the upper left corner.

Study data indicate that T.R.U.E. TEST panels generally adhere well to patient skin. However, in clinical practice, additional circumstances may affect adherence including: 1) excess hair, skin oil or dermatitis at the test site; 2) patient physical activity level; 3) patient perspiration; and 4) climatic extremes, such as high humidity or heat.

If necessary due to patient movements, perspiration or humidity, hypoallergenic tape (e.g., Scanpor®) may be used to better secure T.R.U.E. TEST panels to skin. If hypoallergenic surgical tape is used, it is important that it be applied only to the outside edges of the panels. The excessive use of tape can cause the accumulation of moisture, influencing test results and increasing skin irritation.



**FOR 48 HOURS:** Leave T.R.U.E. TEST panels in place, keep dry and protect from direct sun exposure. Following this period, panels should be removed.

**AT 48 HOURS AND 72-96 HOURS AFTER APPLICATION:** Read skin reactions to T.R.U.E. TEST allergens. This minimum time span is necessary for allergic reactions to develop and for irritant reactions to subside.



**HOT TIP:** Additional readings at 5-7 days after test application can be important. This is especially true for **neomycin** and **p-phenylenediamine**, as these allergens can elicit late reactions.