

INTERPRETATION OF T.R.U.E. TEST® RESULTS

When applied properly and interpreted correctly, patch testing with T.R.U.E. TEST (Allergen Patch Test) is invaluable in diagnosing allergic contact dermatitis. Under ideal conditions, symptom patterns and sites can help differentiate allergic from irritant reactions. For example, earlobe dermatitis or reactions associated with watches, buckles, or gloves tend to be associated with allergic contact dermatitis. By comparison, systemic symptoms such as contact urticaria or respiratory problems are consistent with systemic allergies.

Distinguishing irritant from allergic contact dermatitis can be most challenging. Both types may exhibit similar characteristics and distributions, especially on the hands. For example, both types of dermatitis can be present and persistent, but irritant reactions are often characterized by discoid hand dermatitis or involvement of interdigital spaces. In some cases, irritant and allergic contact dermatitis may coexist due to increased penetration of allergens or irritants into damaged skin.

In addition to irritant contact dermatitis, other skin conditions and skin tone may complicate interpretation of patch test results. The presence of atopic dermatitis, stasis dermatitis, seborrheic dermatitis, nummular dermatitis, cellulitis, urticaria, mycotic infections, pompholyx, and psoriasis can also impact the differential diagnosis.

INTERPRETING AND RECORDING REACTIONS TO T.R.U.E. TEST ALLERGENS



STEP 1. Remove T.R.U.E. TEST Panel 1.1 after 48 hours. This time span is necessary for allergic reactions to develop fully and for irritant reactions to subside. Allow the transient erythema from occlusion to subside for a few minutes and examine the test site for skin reactions.

An identification template is provided for quick identification of causative allergens. Position the identification template so that the notches align with skin markings.

STEP 2. Interpret any skin responses to Panel 1.1 allergens. Skin responses are described on the following pages and are interpreted according to criteria established by the International Contact Dermatitis Research Group, as shown below.

Extreme positive (+++)	Strong positive (++)	Weak positive (+)	Irritant (IR)	Doubtful (?)
Coalescing vesicles, bullous reaction	Erythema, papules, infiltration, discrete vesicles	Erythema, infiltration, discrete papules	Discrete, patchy, follicular, or homogenous erythema with no infiltration	Faint macular or homogenous erythema with no infiltration

ALLERGEN PATCH TEST STANDARD DATA COLLECTION FORM



Lot No. _____
 Date Applied _____
 Date _____
 1st Reading _____
 Date _____
 2nd Reading _____

Patient's Name _____
 Chart No. _____ Age _____ Sex (M/F) _____ Race _____
 Physician's Name _____
 Address _____ Phone _____
 City _____ State _____ ZIP _____

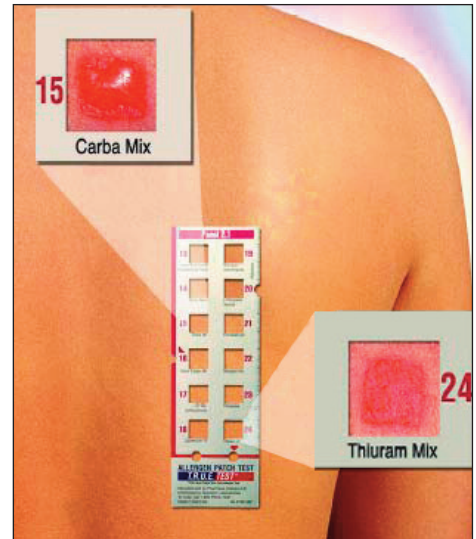
POSITIVE REACTIONS	CLINICAL RELEVANCE		
	Present	Past	Unknown
Allergen No.			

PANEL 1.1		PANEL 2.1		PANEL 3.1	
1 = Nickel Sulfate	7 = Colophony	13 = p-tert Butylphenol Formaldehyde Resin	19 = Mercaptobenzothiazole	25 = Diazolidinyl Urea (Germal II)	26 = Imidazolidinyl Urea (Germal® 115)
1st _____	1st _____	1st _____	1st _____	1st _____	1st _____
2nd _____	2nd _____	2nd _____	2nd _____	2nd _____	2nd _____
2 = Wool Alcohols	8 = Paraben Mix	14 = Epoxy Resin	20 = p-Phenylenediamine	27 = Budesonide	28 = Tixocortol-21-Pivalate
1st _____	1st _____	1st _____	1st _____	1st _____	1st _____
2nd _____	2nd _____	2nd _____	2nd _____	2nd _____	2nd _____
3 = Neomycin Sulfate	9 = Negative Control	15 = Carba Mix	21 = Formaldehyde	29 = Quinoline Mix	
1st _____	1st _____	1st _____	1st _____	1st _____	
2nd _____	2nd _____	2nd _____	2nd _____	2nd _____	

STEP 3. Record interpreted reactions on the *Standard Data Collection Form* (see Section 5).

Interpretations can be annotated as:

- **Irritant - IR**
- **Doubtful - ?**
- **Weak Positive - +**
- **Strong Positive - ++**
- **Extreme Positive - +++**



STEP 4. Repeat the process with T.R.U.E. TEST Panel 2.1 and 3.1, interpreting and recording visible skin reactions.

AT 72-96 HOURS AFTER APPLICATION:

Recall the patient and again interpret skin reactions to T.R.U.E. TEST allergens. Record these second interpretations on the *Standard Data Collection Form* using the annotations described.

This second reading is essential to help identify and confirm allergic reactions and to allow irritant reactions to diminish.

If allergies to neomycin and p-phenylenediamine are suspected, perform additional readings. Because these allergens can elicit late reactions, be sure to interpret tests 5-7 days after T.R.U.E. TEST application. Advise patients to be aware of potential reactions at these sites (a reading template for at-home use may be helpful).

If reactions appear negative – i.e. no visible skin response after multiple readings – the patient may be allergic to substances not included in T.R.U.E. TEST. Consider patch testing with additional substances using Finn Chambers® and additional standardized allergens. Depending on patient history and symptoms, it may be valuable to refer a patient to a contact allergy specialist such as an American Contact Dermatology Society (ACDS) member.

Alternatively, patients with negative test results may be suffering from irritant contact dermatitis or other skin conditions. See the section below entitled “Differential Diagnosis – Negative Reactions” for further information.