

CLINICAL INDICATIONS AND CONTRAINDICATIONS

Dermatitis that is chronic and persistent should be further evaluated based on the results of a thorough exam and detailed health and occupational history. The initial site of the dermatitis and the pattern of spread are important features. These are often more valuable than the nature of the eruption. Both history and symptom patterns are important to establish risk factors and exposure to allergens and irritants.

Allergic contact dermatitis should be suspected and patch testing considered when:

- dermatitis does not improve as expected despite treatment;
- only skin exposed to a possible allergen or irritant is affected;
- dermatitis appears suddenly, and with no past history;
- dermatitis has an unusual pattern or distribution;
- there has been contact with a known allergen; or
- dermatitis persists and involves hands, feet, face, ears, or legs.

T.R.U.E. TEST® (Allergen Patch Test) provides the physician with an objective method for patch testing to the most common allergens that are responsible for the majority of allergic contact dermatitis cases.



INDICATIONS FOR USE

The primary aim of patch testing with T.R.U.E. TEST is to identify (or exclude) contact allergies to the substances included on test panels.

Conditions where patch testing with T.R.U.E. TEST may be indicated:

- Dermatitis that persists or recurs frequently
- Dermatitis that does not respond to treatment
- Presumed or suspected contact dermatitis
- Dorsal or patchy dermatitis on the hands
- Dermatitis with unusual distribution or eruption patterns
- Dermatitis of indeterminate cause
- Facial dermatitis (excluding classical seborrheic dermatitis)
- Discoid dermatitis on the limbs or trunk
- Leg dermatitis, especially when diffuse or associated with leg ulcers
- Foot dermatitis, alone or with hand dermatitis
- Perianal or perineal dermatitis
- Chronic otitis externa
- Atypical allergic symptoms such as angioedema, urticaria, or respiratory problems
- Dermatitis or urticarial reactions after ingestion of suspected allergens

See package insert included with T.R.U.E. TEST for more information.

T.R.U.E. TEST may also be used to determine whether there is a contact allergy confounding the treatment of other types of dermatitis (atopic, seborrheic, venous, palmar and plantar hyperkeratotic, vesiculous, or neurodermatitis) or chronic skin disease, such as leg ulcers or psoriasis. T.R.U.E. TEST may also be used for contact allergy testing in patients with a confirmed or suspected type I latex protein allergy, because the product does not contain natural rubber latex.

CONTRAINDICATIONS

See package insert included with T.R.U.E. TEST for more information.

Avoid using T.R.U.E. TEST in patients with extensive ongoing outbreaks of contact dermatitis: In these patients, patch testing can elicit intense reactions at current and previously affected sites, and false positive results could be obtained. Although the amount of each allergen in the T.R.U.E. TEST panels is small, it may be sufficient to exacerbate severe dermatitis reactions in extremely sensitized patients.

PRECAUTIONS

See package insert included with T.R.U.E. TEST for more information.

T.R.U.E. TEST should only be applied to healthy skin: Test sites should be free of scars, acne, dermatitis, or other conditions that may interfere with test result interpretation. If excessive body hair occurs at the test site, remove with an electric shaver (do not use razors). Very oily skin may be cleaned with mild soap and water. Avoid using alcohol or other irritating substances on the skin prior to testing. Do not apply T.R.U.E. TEST panels to recently tanned or sun-exposed skin because this may increase the risk of false negatives.

Avoid patient use of immunosuppressants and immunomodulators prior to and during testing: Oral steroids (equivalent to 10 mg or more of prednisolone) may suppress positive T.R.U.E. TEST reactions and increase the risk of false negatives. The biological half-life of these drugs varies among patients and ranges from hours to days. For optimal patch test results, oral steroids should be avoided for approximately 2 weeks prior to testing and during patch testing.



The effect of concomitant antihistamine use during patch testing with T.R.U.E. TEST is unknown. Some dermatologists believe systemically administered antihistamines have no effect on patch test results, but there is limited conclusive data. The few published studies of oral antihistamine administration during conventional patch testing indicate that some compounds may increase the risk of false negatives or compromise interpretation of positives. Therefore, due to the risk of suboptimal results, oral antihistamine use before and during T.R.U.E. TEST patch testing it is not advised.

The effect of cyclosporine therapy on T.R.U.E. TEST results has not been studied and is unknown. When used during conventional patch testing, two published clinical studies suggest that treating patients briefly with oral cyclosporine may help distinguish true-positive reactions from weak or false-positive reactions, and may be helpful in patients with excited skin syndrome.

Topical steroids, antihistamines and other immunosuppressants (e.g., tacrolimus) may be used on non-test areas, but should be avoided on potential patch test areas prior to and during testing.

The safety and efficacy of T.R.U.E. TEST patch testing in children is unknown: During pre-market approval testing of T.R.U.E. TEST, most clinical trial protocols excluded patients under the age of 16. Since that time published clinical studies with T.R.U.E. TEST have reported its use in pediatric patients ranging from 6 months to 14 years of age, and positive reactions occurred at rates similar to previously published pediatric studies that used conventional patch testing.



Published pediatric studies with T.R.U.E. TEST have also reported transient positive reactions, irritant reactions to the tape, and localized discomfort during patch testing (see *Clinical Studies*).

However, application of T.R.U.E. TEST in children is considered an off-label use in the United States even when supported by current medical care guidelines.

The safety and efficacy of T.R.U.E. TEST patch testing in women who are pregnant or breast-feeding is unknown: No adequate and well-controlled trials of T.R.U.E. TEST have been performed in pregnant women or animals. It is unknown if T.R.U.E. TEST allergens may harm a developing fetus or affect reproduction capacity in women. T.R.U.E. TEST has been assigned a pregnancy Category C level of fetal risk by the Food and Drug Administration. Therefore, T.R.U.E. TEST should only be applied to pregnant women if clearly needed.



T.R.U.E. TEST should also be used cautiously in women who are breast-feeding because the potential for panel allergens appearing in breast milk is unknown. It is also unknown if infants or children consuming this breast milk could be affected by the presence of T.R.U.E. TEST allergens.

Keep T.R.U.E. TEST panels dry during testing: Patients should avoid activities that cause excess perspiration or expose the test area to excess moisture. Showering is not advised. Sponge baths are acceptable provided the patient protects the panels and surrounding skin from excess moisture.

WARNINGS

See package insert included with T.R.U.E. TEST for more information.

- Itching and burning
- Discomfort
- Excited skin syndrome
- Sensitization
- Hyperpigmentation
- Exposure to potential carcinogens

Carefully evaluate the use of T.R.U.E. TEST in patients with a known history of severe systemic and/or local reactions to any of the allergen components or inactive substances included in the T.R.U.E. TEST panels before application. If patch testing is performed in these patients, proper medical precautions should be observed.

The safety and efficacy of repetitive testing with T.R.U.E. TEST are unknown. Sensitization or increased reactivity to one or more of the allergens may occur. The benefits of repeat testing should therefore be evaluated carefully against possible risks based on patient history and symptoms. In addition, the safety and efficacy of patch testing children using T.R.U.E. TEST is not yet established.

Itching and burning sensations: Patients should be warned that these reactions are common with patch testing, and may be severe in extremely sensitive patients. Medication may be considered necessary to relieve such symptoms, and on rare occasions it may be necessary to remove T.R.U.E. TEST sooner than 48 hours because of severe itching or burning sensations.

Discomfort: Extremely sensitive patients may exhibit strong positive (+++) reactions that may be bullous or ulcerative with pronounced erythema, infiltration, and coalescing vesicles. Dermatitis flare-ups may occur in some patients.

If the discomfort and reaction is severe, the patient can be advised to carefully cut out the offending allergen(s) square from the T.R.U.E. TEST panel. The patient may also be treated with a topical corticosteroid or, in rare cases, with a systemic corticosteroid.

Excited skin syndrome: This is a state of hyper-reactivity induced by strong positive test reactions or by outbreaks of dermatitis on other body parts. It is also known as “angry back” syndrome. If it occurs, excited skin syndrome may confound the results of T.R.U.E. TEST. Therefore, test results should be evaluated carefully in patients with multiple positive contact allergen test results. Retesting may be necessary to determine which reactions were falsely positive.

Sensitization: Patients may be sensitized to a substance included on a T.R.U.E. TEST panel during contact allergen testing but this is extremely rare. The potential for sensitization or increased reactivity to one or more allergens with repetitive testing is unknown.

The appearance of reactions after 7 days or later, with no preceding reaction, may suggest sensitization. However, care must be taken not to confuse these with legitimate late reactions, such as those that can occur with neomycin sulfate and *p*-phenylenediamine.

Potential exposure to carcinogens: Nickel refinery dust, nickel sulfite, and formaldehyde are known carcinogens. Nickel sulfate, potassium dichromate, cobalt dichloride, epoxy resin, and thiuram mix are suspected carcinogens. The potential effects of using very low concentrations of these substances for single or multiple applications are currently unknown.

Hyperpigmentation: This reaction occurred at the T.R.U.E. TEST application site during healing and was noted in approximately 11% of patients tested. It is more likely to occur in patients with extreme positive reactions and is more common in dark-skinned individuals. It may also occur in some patients with irritant reactions.

Sunlight or ultraviolet light exposure after patch test removal may also lead to hyperpigmentation of some test sites. Healing usually takes 5 days to 2 weeks but may require additional time to resolve in some patients.

POTENTIAL ADVERSE EVENTS

See package insert included with T.R.U.E. TEST for more information.

Adverse reactions may include:

- Pruritus
- Erythema
- Hyperpigmentation
- Scarring
- Contact urticaria
- Delayed reactions
- Irritation due to adhesive tape

Adverse events reported with the use of T.R.U.E. TEST are normally mild and localized to the test site. The most common are **pruritus** and burning, **erythema**, and **hyperpigmentation**. If these reactions are severe enough, it may be advisable to remove a T.R.U.E. TEST allergen or panel sooner than 48 hours and initiate treatment with a topical (or systemic) corticosteroid.

Irritation from the adhesive tape in T.R.U.E. TEST panels has been reported in 0.8 to 6% of patients in clinical studies and may persist for up to 3 weeks after testing. T.R.U.E. TEST adhesive tape is a porous, hypoallergenic surgical tape made of rayon fibers with a polyacrylate adhesive that includes vinyl acetate, 2-ethylhexyl acrylate, hydroxyethyl methacrylate, glycidyl methacrylate.

Systemic symptoms such as urticaria (generalized), anaphylaxis, or other type I hypersensitivity reactions have not been reported with the use of T.R.U.E. TEST. However, published case reports have noted that several contact allergens can elicit systemic reactions such as urticaria and respiratory symptoms. As noted above, the use of T.R.U.E. TEST in patients with a known history of severe reactions to any of the allergen components or inactive substances included in the T.R.U.E. TEST should be carefully evaluated and adequate precautions taken before testing.