

## INTRODUCTION

### CONTACT DERMATITIS IS COMMON AND COSTLY

Allergen exposure is influenced by climate, occupation, cultural habits, and regulations. The prevalence of contact allergy against specific allergens differs among countries as a result in changes and developments in surrounding environments and societies. (Thyssen et al 2007) In the United States, estimates of prevalence range from 5% to 50%, depending on population and defining criteria. According to a 2005 report by The Society for Investigative Dermatology and The American Academy of Dermatology, contact dermatitis is associated with more than 9 million physician office visits and as many as 10% of all dermatology clinic visits. Treating contact dermatitis costs approximately \$1.4 billion annually, with significant losses (~\$500 million) attributed to missed workdays and low productivity. (Bickers et al. 2006) In the UK, occupational contact dermatitis is the most frequently reported occupational skin disease in developed countries and accounts for between 70% and 90% of all reported cases of occupational skin disease. The annual population incidence of occupational contact dermatitis ranges from an estimated 5.7 to 101 cases per 100,000 workers per year. The most reliable studies estimate the incidence to be between 11 and 86 cases per 100 000 workers per year. (Nicholson et al. 2010) Experts believe these numbers may underestimate the impact of contact dermatitis.

### ALLERGIC OR IRRITANT CONTACT DERMATITIS?

Although irritant contact dermatitis is thought to be more common, recent studies suggest that allergic contact dermatitis may be responsible for nearly half of dermatitis cases, especially when work related. (Templet et al., 2004; Kucenic and Belsito, 2002) The two major diagnoses of contact dermatitis are irritant (ICD) and allergic (ACD) contact dermatitis. ICD is a non-specific inflammatory dermatosis, primarily caused by the toxicity of chemicals on the skin cells, hence, triggering inflammation by activation of the innate immune system. ACD, however, corresponds to a delayed-type hypersensitivity response and the skin inflammation is mediated by antigen specific T cells. (Nosbaum et al. 2009)

	<b>Allergic Contact Dermatitis</b>	<b>Irritant Contact Dermatitis</b>
<b>Immune Reaction</b>	T-cell mediated; Localized, but may spread beyond contact site	No immune system involvement; Inflammation at contact site
<b>Most Common Sources</b>	Nickel, fragrance components, rubber processing chemicals, neomycin, preservatives, cobalt and potassium chromate	Detergents, acids, alkalis, oils, solvents, or exposure to abrasive, caustic or wet environments
<b>Onset</b>	Begins within hours or days of exposure	Begins within minutes or hours of exposure
<b>Typical Presenting Symptoms</b>	<ul style="list-style-type: none"><li>• Pruritis, papules, vesicles, edema, fissures, erythema, and oozing</li><li>• May spread beyond contact site</li></ul>	<ul style="list-style-type: none"><li>• Skin dryness, fissuring and thickening; edema and erythema</li><li>• Distribution localized to contact site</li></ul>

**Allergic contact dermatitis:** In already sensitized individuals, this immunologic response is elicited by contact with a specific allergen or closely related chemical. Symptoms typically manifest 24 to 72 hours after allergen exposure, vary in intensity and often include itching and vesiculation.

More than 3,000 chemicals are reportedly capable of causing allergic contact dermatitis but relatively few allergens account for most cases. These common allergens form the basis of diagnostic patch testing that is used to differentiate allergic from irritant contact dermatitis.

**Irritant contact dermatitis:** This non-specific inflammatory condition develops after skin is exposed to substances that are physically, chemically or mechanically traumatizing. Symptoms are usually confined to the area of contact, recur with additional irritant exposure and may be difficult to distinguish from allergic contact dermatitis.



## WHY PATCH TEST?

Patch testing is a simple bioassay that helps diagnose and identify causative agent(s) in persistent contact dermatitis. Even experienced dermatologists can miss 20% to 80% of contact allergies when using history alone. (Fischer and Maibach 1990) Patient symptoms, history and physical exam are rarely sufficient. Patch test results can provide crucial information that identifies the offending allergen(s). (Lachapelle and Maibach 2009)

Patient interviews show that patch testing has a positive impact, with a perceived improvement in symptoms. (Paul et al., 1995) Patients learn to identify and avoid allergens, protect their skin from irritants and other allergens, and use therapies appropriately.

**PATCH TESTING CAN HELP REDUCE THE DURATION OF PATIENT SYMPTOMS**

Early diagnosis and patient education are associated with improved prognosis, and may be more valuable than job changes. (Cahill et al., 2004; Woo et al., 2003) In a retrospective study of 270 patients with allergic contact dermatitis, patient disease duration after contact allergen testing and treatment was half that of patients treated without testing. (Diepgen 2008; Rajagopalan et al., 1998) Not surprisingly, 84% of patients felt patch testing was worthwhile.

**WITHOUT PATCH TESTING:** 265 Days of symptoms (~ 9 months)  
**WITH PATCH TESTING:** 122 Days of symptoms (~ 4 months)  
(Lachapelle and Maibach 2009)

An earlier study reported that symptom duration decreased by half in patients with allergic contact dermatitis who were patch tested.

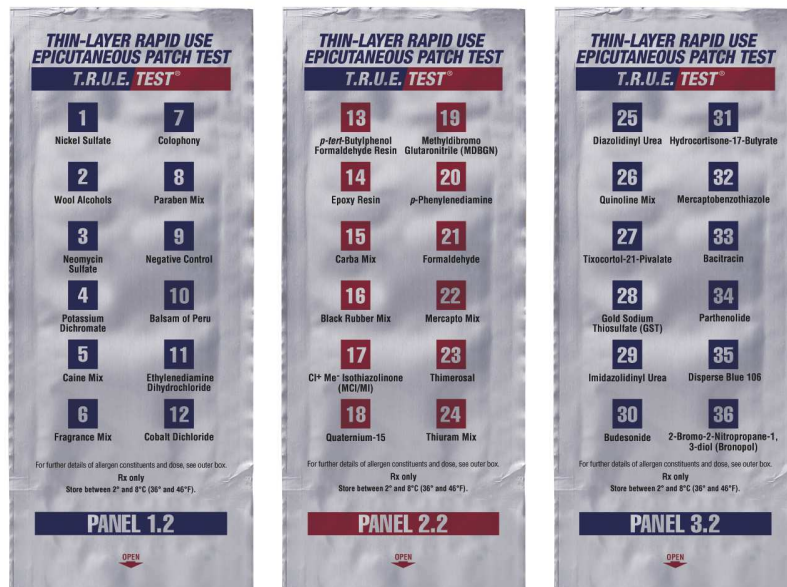
Patients can suffer with contact dermatitis for up to 40 years. (Holness and Mace, 2001; Bickers et al. 2006) Unresolved dermatitis costs patients in terms of multiple doctor visits, prescriptions, over-the-counter medicaments, as well as lost time and productivity. The prognosis for these patients with persistent unresolved dermatitis is poor, and most will experience discomfort, embarrassment and other factors that diminish their quality of life. (Holness, 2001; Ayala et al., 2010)

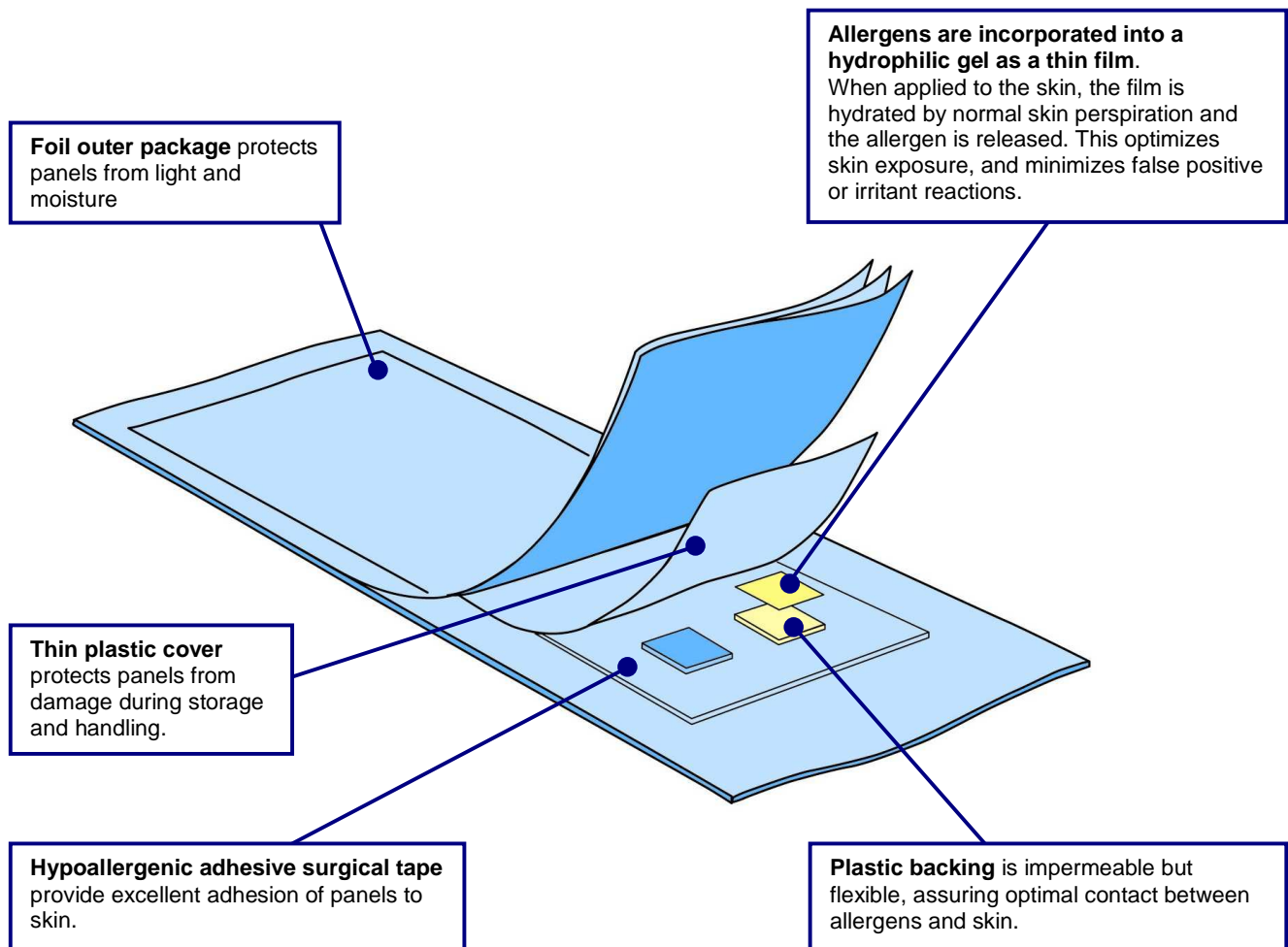
## T.R.U.E. TEST® (ALLERGEN PATCH TEST) FEATURES AND BENEFITS

T.R.U.E. TEST is a ready-to-use patch test for the differential diagnosis of persistent dermatitis. It contains 35 allergens and allergen mixes that are responsible for the majority of cases of allergic contact dermatitis.

**T.R.U.E. TEST is convenient to use:** The allergens and allergen mixes require no additional mixing or handling, and are standardized in two ready-to-use T.R.U.E. TEST panels. The use of premeasured allergens minimizes staff preparation time.

**T.R.U.E. TEST unique design helps ensure accuracy and reproducibility:** T.R.U.E. TEST allergens and allergen mixes have been incorporated into hypoallergenic, dehydrated, hydrophilic gels attached to a waterproof backing. When applied to the skin, perspiration and transepidermal water loss rehydrate these gels, thereby releasing the allergens onto the skin. The test also contains one uncoated polyester patch as a negative control, which can be used as a baseline for interpreting doubtful or minimal reactions.





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

T.R.U.E. TEST allergens and allergen mixes are formulated for increased stability and distributed homogeneously. This reduces the potential for false-positive and irritant reactions. The allergen dose or concentration has also been optimized to be sufficient for eliciting allergic reactions in weakly sensitized patients, yet low enough to minimize the risk of iatrogenic sensitization. In addition, the panels are wrapped in an airtight foil pouch for protection from light and moisture.

**T.R.U.E. TEST can help quickly resolve patient dermatitis:** Nearly one-quarter to two-thirds of patients with ACD will test positive to at least one T.R.U.E. TEST allergen. (Cohen et al., 1997; Marks et al., 1998; Bickers et al. 2006) Some of these reactions will correlate to allergen exposure, while others may suggest allergies to related, cross-reactive substances. Negative results are also common and have diagnostic value in eliminating suspected allergies as well as helping physicians identify other potential allergens or irritants.

T.R.U.E. TEST may also be used to assess the complicating role of contact allergies in recalcitrant cases of atopic dermatitis, seborrheic dermatitis, hypostatic eczema, dyshidrotic eczema, stasis dermatitis, and psoriasis. Consider patch testing as soon as possible for new and referred patients with a prior history of recurring dermatitis, and for established patients returning due to persistent dermatitis.



## T.R.U.E TEST CASE PRESENTATIONS

These examples illustrate the importance of patch testing to distinguish allergic versus irritant contact dermatitis. Chemical exposure, history and symptoms often support either diagnosis. Since allergic and irritant contact dermatitis cannot be differentiated easily based on exams or histories alone, patch testing was essential for an accurate diagnosis.

**Case History #1:** A radiology technician presented with a 6-month history of pruritic dermatitis on his hands. Although temporarily responsive to corticosteroid therapy, he had developed recurrent lesions that were fissured and erythematous. The patient had a history of childhood atopy, but was otherwise unaware of other allergies.

Exposure history: Working in health care increased the risk of exposure to multiple allergens, especially those related to rubber gloves and other rubber products. The patient acknowledged exposure to a number of potential allergens and irritants, including photographic developing chemicals, soaps and cleansers, sterilizing and disinfecting chemicals, rubber gloves, and metal equipment. At home, he was also exposed to preservatives, fragrances, and other components of topical products used to treat his skin condition.



Patch test results and patient outcome: This patient tested positive to carba mix and thiuram mix, which are substances used in the manufacture of natural and synthetic rubber products. The patient was counseled to avoid direct contact with rubber products, including gloves. The patient's dermatitis resolved when vinyl gloves replaced the rubber gloves at work.

**Case History #2:** A 60-year-old homemaker presented with a history of pruritic eruptions. The patient's palms exhibited severe scaling, fissuring and erythema. Fingertip periungual areas were also involved, but not the dorsa of the hands. Patient's skin was otherwise clear, except for localized psoriasis of the left elbow and knee.

The patient's history indicated that her family physician had prescribed a topical corticosteroid cream and advised her to wear rubber gloves and use a moisturizer. When this did not correct the problem, she sought the advice of a dermatologist. The dermatologist prescribed a more potent topical corticosteroid, advised her to avoid wet work, and suggested she wear vinyl gloves because she might be allergic to rubber. When her condition continued to worsen despite these measures, she sought the opinion of second dermatologist.



Patch test results and patient outcome: The second dermatologist patch tested the patient, which revealed the patient's allergy to quaternium-15, a formaldehyde-releasing preservative found in many different creams and lotions. The patient's moisturizer (advised by her original physician) contained quaternium-15, which was exacerbating her original irritant contact dermatitis.

After selecting skin care products without quaternium-15, the patient was able to successfully manage her skin's health with this moisturizer, gloves, and the occasional use of a topical corticosteroid. Her psoriasis has remained stable, and without hand involvement.