

Product Information:

TRUE Test is a ready to use patch test for the diagnosis of allergic contact dermatitis.

Indication

- Confirmation of allergic contact dermatitis where a history from the patient suggests sensitisation to one or more of the allergens comprising TRUE Test
- To exclude allergic contact dermatitis in the differential diagnosis of other types of eczema and dermatological conditions

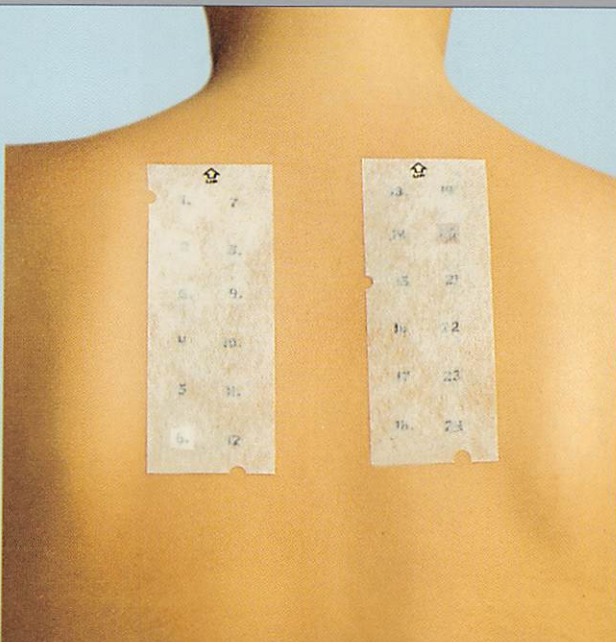
Description:

- The test consists of two self-adhesive tape strips; both covered with a protection sheet. For protection against light and air the strips are contained in airtight and opaque pouches.
- The two strips contain 24 polyester patches coated with a dry film containing a specific allergen or allergen mix.
- The allergens are selected according to international recommendations and this standard tray covers approximately 70% of allergic contact dermatitis reactions.
- A classical type IV delayed hypersensitivity reaction within 6-96 hours of the test application denotes a positive response to an allergen patch. Clinical signs of a positive contact dermatitis reaction are erythema and a palpable dermal inflammatory infiltrate at the test area, oedema, papules and vesicles.
- For the most accurate test results the strips should be removed from the patient's back after 48 hours and evaluated after 72-96 hours.

The standard patch test panel

The standard panel consists of 24 patches, with 12 on each of the two panels. Each patch is coated with a thin dry film that incorporates a specific allergen or allergen mixture in a calibrated dose.

Panel 1		
Patch	Allergen	Micrograms/cm ²
1.	Nickel sulphate	200
2.	Wool alcohols	1000
3.	Neomycin sulphate	230
4.	Potassium dichromate	23
5.	Caine mix	630
6.	Fragrance mix	430
7.	Colophony	850
8.	Epoxy resin	50
9.	Quinoline mix	190
10.	Balsam of Peru	800
11.	Ethylenediamine dihydrochloride	50
12.	Cobalt chloride	20



Panel 2		
Patch	Allergen	Micrograms/cm ²
13.	p-tert-Butylphenol formaldehyde resin	50
14.	Paraben mix	1000
15.	Carba mix	250
16.	Black rubber mix	75
17.	Cl+Me-Isothiazolinone (Kathon CG)	4
18.	Quaternium-15	100
19.	Mercaptobenzo-thiazole	75
20.	p-Phenylenediamine	90
21.	Formaldehyde (N-hydroxymethyl succinimide)	180
22.	Mercapto mix	75
23.	Thiomersal	8
24.	Thiuram mix	25

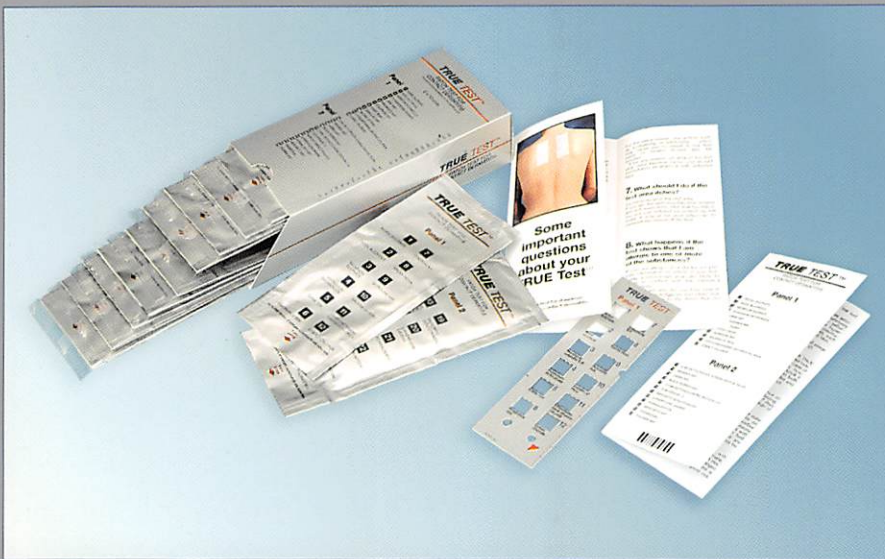
FOR THE DIAGNOSIS OF
ALLERGIC CONTACT
DERMATITIS

TRUE TEST[®]

- A ready-to-use patch test
- Fast and convenient to apply
- Time-saving
- Reliable and standardised
- Secure reproducible results



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LABORATORIES AS



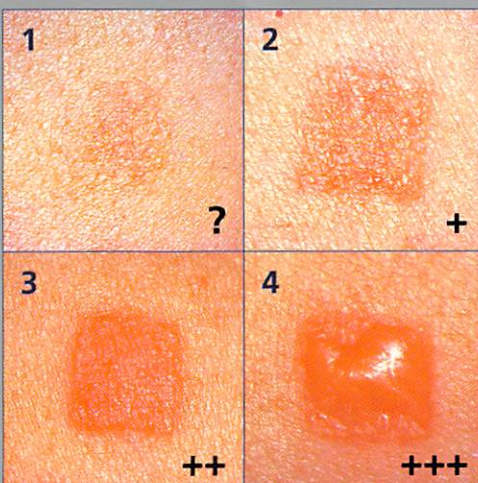
To assist when using TRUE Test, interpreting the results and advising the patient; TRUE Test systems includes:

1. Templates to identify each allergen
2. Patient information leaflets which answer the most commonly asked questions about the test procedure
3. A product manual to assist the physician
4. Information to the patient about:
 - The nature of the allergen
 - Where the allergen is found
 - How to avoid it and alternatives available

Benefits

- TRUE Test patch test system is ready to apply and time-saving
- TRUE Test is safe and reliable, and the results are highly reproducible
- TRUE Test standard procedures used in manufacturing and quality control guarantee uniform quality and consistent performance

Examples of typical patch test reactions:



Doubtful reaction - ?

Weak positive reaction - +

Strong positive reaction - ++

Extreme positive reaction - +++

Application instructions



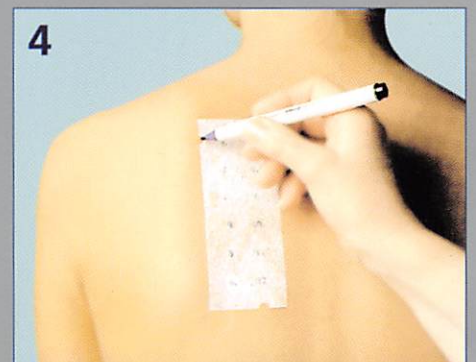
1 Peel open the package and remove the test panel



2 Remove the protective plastic, covering the test surface of the panel. Be careful not to touch the test substances



3 Position the test on the patient's back (app. 5 cm from the midline) so that the no. 1 allergen is in the upper left corner. From the centre of the panel, smooth outward toward the edges, making sure each allergen makes adequate contact with the skin



4 With a medical marking pen, indicate the location of the two notches on the panels

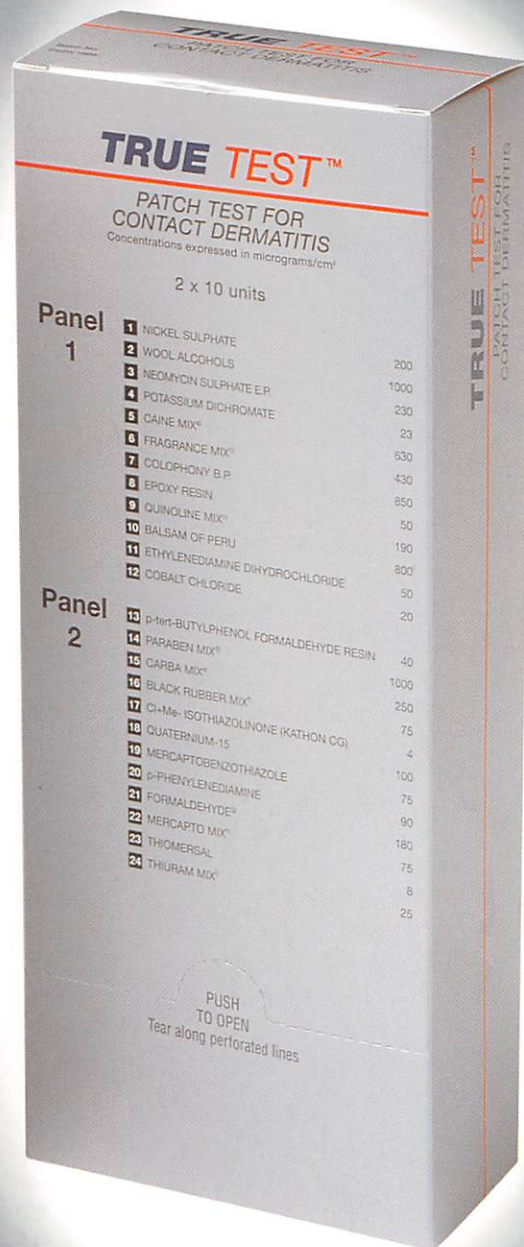
Precautions

- Patch testing should only be conducted on healthy skin, free from dermatitis and as far as possible from acne, scars or any other condition that may interfere with the interpretation of test results.
- Safety and efficacy studies with TRUE Test has not been conducted in infants and breastfeeding women, neither is reproduction studies performed.
- Avoid oral or topical steroids.

Availability and Storage

- TRUE Test is supplied in boxes of 10 standard tests (2 x 10). The 24 patches are split onto two tape strips; panel 1 and panel 2, each packed in an airtight pouch.
- Storage at + 2 to 8° C
- Shelf life under the above conditions: 24 months.
- The expiry date is stated on the package

TRUE Test® – **Pharmaceutical form:** Self-adhesive plaster for cutaneous use. **Excipients:** Purified water, ethanol, acetone, sodium carbonate, sodium bicarbonate, povidon 90, hydroxypropyl cellulose, methyl cellulose, β -cyclodextrin. **Therapeutic indication:** Diagnosis of allergic contact dermatitis. **Contraindications:** Extensive ongoing active dermatitis. **Undesirable effects:** *Local:* A positive test reaction usually disappears within 1-2 weeks. On rare occasions, test reactions may persist for a month, leaving an area of transient hypopigmentation. Irritation caused by the surgical tape adhesive may occur, but usually disappears rapidly. *General:* Sensitisation. **Dosage:** A dosage for each allergen has been established that is high enough to evoke a reaction even in weakly sensitised patients, yet low enough to minimize the risk of irritant reaction. The test is best applied on the upper part of the back, about 5 cm from the midline. **Contents of container:** TRUE Test® consists of two panels of self-adhesive surgical tape, each incorporating 12 allergens or allergen-mix. TRUE Test® is supplied in multipack cartons with 10 test strips of each panel. **Shelf life:** 24 months. **Sale:** Prescription product. **Date:** 03/2003.



Power Grafik 03.2003

For further information – please contact:



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