TRUE TEST™

PATCH TEST FOR ALLERGIC CONTACT DERMATITIS

Panel 1

	Labelled amount µg/cm$_2$
1. Nickel sulphate	200
2. Wool alcohols	1000
3. Neomycin sulphate	230
4. Potassium dichromate	23
5. Caine mix a)	630
6. Fragrance mix b)	430
7. Colophony	850
8. Epoxy resin	50
9. Quinoline mix c)	190
10. Balsam of Peru	800
11. Ethylenediamine dihydrochloride	50
12. Cobalt chloride	20

Panel 2

13. p-tert Butylphenol formaldehyde resin	50
14. Paraben mix d)	1000
15. Carba mix e)	250
16. Black rubber mix f)	75
17. Cl+Me-Isothiazolinone (Kathon CG)	4
18. Quaternium-15	100
19. Mercaptobenzothiazole	75
20. p-Phenylenediamine	90
21. Formaldehyde g)	180
22. Mercapto mix h)	75
23. Thiomersal	8
24. Thiuram mix i)	25

a) Five parts of benzocaine, one part of cinchocaine hydrochloride and amethocaine hydrochloride.

b) Five parts of geraniol and oak moss, four parts of hydroxycitronellal and cinnamylalcohol, two parts of cinnamaldehyde and eugenol and one part of isoeugenol and amylcinnamaldehyde.

c) Equal weights of clioquinol and chlorquinaldol.

d) Equal weights of methyl parahydroxybenzoate, ethyl parahydroxybenzoate, propyl parahydroxybenzoate, butyl parahydroxybenzoate and benzyl parahydroxybenzoate.

e) Equal weights of diphenylguanidine, zinc diethyldithiocarbamate and zinc dibutyldithiocarbamate.
f) Two parts of N-isopropyl-N'-phenyl paraphenylenediamine, five parts of Ncyclohexyl-N'-phenyl paraphenylenediamine and five parts of N,N'-diphenyl paraphenylenediamine.
g) Actually contains N-hydroxymethyl succinimide.
h) Equal weights of morpholinyl mercaptobenzothiazole, N-cyclohexyl benzothiazyl sulphenamide and dibenzothiazyl disulphide.
i) Equal weights of disulfiram, dipentamethylenethiuram disulphide, tetramethylthiuram disulphide and tetramethylthiuram monosulphide.

Excipients: Sodium carbonate, Sodium bicarbonate, Polyvidone 90, Hydroxypropyl cellulose, Methylcellulose, ß-Cyclodextrin.

DESCRIPTION

TRUE Test™ is a ready-to-use patch test indicated for the diagnosis of allergic contact dermatitis. It consists of 24 of the most common allergens/allergen mixes.

The test consists of 2 pieces of surgical tape with 24 polyester patches which are coated with a film containing a specific allergen or allergen mix.

Due to the instability of some allergens on panel 2, a desiccant paper has been included in the pouch. This is to assure stability throughout the shelf-life.

CLINICAL PHARMACOLOGY

A positive response to the patch test is a classical delayed hypersensitivity reaction (type IV), which can appear within 6-96 hours after exposure.
The cell-mediated response involves the Langerhans' cell and T-lymphocytes which interact and produce lymphokines. These lymphokines then form lymphocyte clones which trigger macrophages to cause a cutaneous inflammation. (1)

Clinical signs of a positive allergic contact dermatitis reaction are: erythema, oedema, papules, vesicles and a palpable dermal inflammatory infiltration at the test area.

INDICATIONS AND USAGE

TRUE Test™ is indicated primarily for the diagnosis of allergic contact dermatitis in patients whose history suggests sensitization to one or more of the substances in the test panel.

To exclude sensitization as a possible aetiology, TRUE Test™ may also be used adjunctively to evaluate other eczemas (atopic seborrhoeic, venous, palmar and plantar hyperkeratotic eczema, vesiculosis or neurodermatitis) and other dermatological diseases, such as leg ulcers and psoriasis that do not heal.

A clinical history that suggests a contact allergy should be confirmed with a patch test. (2)

CONTRAINDICATIONS

The limited amount of allergen on each TRUE Test™ patch which penetrates the skin will rarely induce a flare-up of dermatitis. In the case of *extensive ongoing contact dermatitis,* however, the test should not be applied since it may provoke an intensified reaction on both the present and previously affected sites and may also cause a falsepositive test result.

WARNINGS

Occasionally sensitization to a substance on the test panel may occur when patch testing.

A test reaction that appears later than 7 days after application of the test may be a sign of contact sensitization. (3)

Excited skin syndrome (angry back) is a state of hyperactivity induced by dermatitis on other parts of the body or by a strong positive skin-test reaction. Therefore, test results should be evaluated carefully in patients with multiple, positive, concomitant patch test results. To determine which reactions are false-positive, re-testing at a later date may be necessary. (4)

A potential carcinogenic risk exists with nickel sulphate, potassium dichromate, cobalt chloride, epoxy resin and thiuram mix.

However, due to the low content of allergen and brief contact period (48 hours), there is no reason to suspect that a carcinogenic risk exists with TRUE Test™.

PRECAUTIONS

General:

TRUE Test™ may be administered throughout the year. However, in summertime excessive sweating and exposure of the test site to the sun are to be avoided.

TRUE Test™ should be applied only to healthy skin that is free of acne, scars, dermatitis, or any other condition that may interfere with test results.

Since steroids may suppress a positive test reaction, use of topical steroids on the test site or oral steroids (equivalent to 10 mg prednisolone) should be discontinued for at least two weeks prior to testing.

If a severe patch test reaction develops, the patient may be treated with a topical corticosteroid preparation or, in rare cases, a systemic corticosteroid.

Pregnancy and pediatric use:

The test is not recommended to be applied to the skin of pregnant and breast-feeding women nor children.

ADVERSE REACTIONS

General:

A flare-up of dermatitis may be observed when testing during an active phase of dermatitis. Sensitization (see warnings).

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.

DOSAGE AND ADMINISTRATION

Dosage:

A dosage level for each allergen has been established which is high enough to evoke a reaction even in weakly sensitized patients, yet low enough to minimize the risk of irritant reaction.

Administration:

See under Application Instructions (also available on the back of each TRUE Test™ package).

Interpretation:
The reaction should be read at 72-96 hours. If a reading at 48 hours is considered, this evaluation must be completed with a reading at 72-96 hours after test application, when allergic reactions are fully developed and mild irritant reactions have faded.

Neomycin sulphate and p-phenylenediamine, however, sometimes cause reactions which may not appear until 4-5 days after the application. Patients should be instructed to report this. If appropriate, an additional office visit will verify a late reaction.

An identification template is provided with each package of TRUE Test™ for quick identification of any allergen which causes a reaction.
To assure correct positioning, marks on the skin should correlate with the notches on the template.

The interpretation method recommended by the International Contact Dermatitis Research Group and the North American Contact Dermatitis Group is:

? Doubtful reaction, faint macular erythema only

\+ Weak (nonvesicular) positive reaction
- erythema
- infiltration
- possible papules

++ Strong (vesicular) positive reaction
- erythema
- infiltration
- papules
- vesicles

+++ Extreme positive reaction
- bullous reaction

\- Negative reaction

IR Irritant reaction of different types

NT Not tested

Note:

Patients showing a negative reaction may still be allergic to other substances not included in these test panels. Re-testing or testing with complementary substances may be indicated.

A positive test reaction should meet the criteria for an allergic reaction (papular or vesicular erythema and infiltration)

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Pustules, as well as patchy follicular or homogeneous erythema without infiltration are usually signs of irritation and do not indicate allergy.

False-negative results may occur.

What is important in evaluating a positive test response is not the number of pluses assigned to the test response, but the determination of whether the response is a truly positive reaction (caused by allergy) or a non-specific irritant reaction.

STORAGE:

Store TRUE Test™ at 2 - 8°C. The expiry date is stated on the package.

APPLICATION INSTRUCTIONS

1) Peel open the package and remove the test panel.

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

3) Position the tests next to the midline on the patient's back so that allergen Nos. 1 and 13 point to 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 each panel.

The test should be applied to healthy skin that is free of acne, scars, dermatitis or any other condition that might interfere with interpretation of results (see Precautions).

The test is best applied on the upper part of the back.

However, the outer part of the upper arms is also acceptable.

The patient should wear TRUE Test™ for a minimum of 48 hours without removing it and be careful not to wet the test area. Following this period, the test is removed, either by the physician or patient.

REFERENCES

1. Roitt I, Brostoff J, Male D: Immunology, ed 1. St. Louis, Toronto, CW Mosby Co, 1985, chapter 22, pp 1-10.
2. Calnan C.D.: The use and abuse of patch test, in Maibach HI, Gellin GA (eds): Occupational and Industrial Dermatology, Chicago Year Book Medical Publishers, Inc. 1982, p 35.
3. Fisher A: Contact Dermatitis, ed 3, Philadelphia, Lea & Febiger, 1986, pp 14-15.
4. Bruynzeel DP, Maibach HI: Excited Skin Syndrome (Angry Back). Arch Dermatol 122:1986, pp 323-328.

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