Practice Parameter: Clinical Guidelines for Patch Test



Indian Academy of Pediatrics – Allergy and Applied Immunology Chapter

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INTRODUCTION:

Patch testing is an essential investigation to identify specific allergens in allergic contact dermatitis (ACD) or, in some cases, diagnose ACD. ACD is characterized by maculopapular rash with or without exfoliation of the skin with varying degrees of dryness and itchiness when the skin comes in contact with an offending allergen or irritant. ACD is a T-cell-mediated delayed type IV reaction. An offending allergen is detected by placing it on the skin in small wells and occluding them for 48 hours, thereby creating a mini-response due to the offending agent. The reaction is then read after removing the covering occlusion at 48 hours, 72 or 96 hours, and finally after 7 days. This process of detecting the allergen causing ACD is called 'Patch Testing.' It is based on the principle that in sensitized individuals, primed antigen-specific T lymphocytes of the Th1 phenotype circulate throughout the body and can recreate a delayed-type hypersensitivity reaction when non-irritating antigen concentrations are applied to normal skin.

I. INDICATIONS FOR PATCH TESTING:

- Persistent eczematous eruptions when contact allergy is suspected.
- •Any chronic dermatitis, especially when involving the hands, feet, face, or eyelids.
- Eczematous dermatitis in individuals involved in high-risk occupations for contact dermatitis (eg, health care workers, dental assistants, cosmetologists, machinists, or rubber and plastic workers).

- •Dermatitis of unknown etiology.
- Worsening of a previously stable dermatitis.

Patch testing **may also be indicated** when allergic contact dermatitis (ACD) is suspected as a complication of:

- Atopic dermatitis/Stasis dermatitis/Seborrheic dermatitis
- Nummular eczema/Asteatotic eczema
- Psoriasis

II. METHOD OF PATCH TESTING:

A. Precautions before doing the patch test

- Oral steroids should be stopped at least 3 weeks before testing & topical steroids for at least 1 week before patch testing.
- Skin where patch testing needs to be done should not be exposed to ultraviolet light for at least a month before testing.
- Immunosuppressive drugs need to be stopped.
- Do not perform it on pregnant and lactating women.
- Patch testing should be deferred in extensive active dermatitis/ eczematous skin.
- Antihistamines do not interfere with the test as ACD is a type IV cell-mediated reaction.
- B. **Preparation of patch test site:** Remove the hairs by snipping and degreasing with ethanol or other solvents.
- C. Patch test sites: Upper back, lateral aspect of upper arm, and upper thigh.
- **D.** Age group: No specific age cut-off. It can be done in infants as early as 3 months old.

E. Which allergens to choose?

With the increasing use of cosmetics, dyes, tattoos, artificial colors, synthetic materials, and perfumes, ACD cases are on the rise. A detailed history and a thorough clinical examination are a must before starting a patch test. But, due to the complexity of the products and multiple products used in daily life, it becomes difficult to decide on the allergens. Thus, Standard (baseline) or screening series of contact allergens, which are designed to include the most common sensitizers responsible for ACD in a given region, are recommended as the initial battery for patients undergoing patch testing. The standard series are revised regularly, as new allergens are identified as a cause of ACD. Supplemental series of patch tests suitable for specific exposures, including workplace exposures, are available to complement the standard series (eg, hairdressers, dental, shoe, lip, and stomatitis, or cosmetic series). If a standard series and supplemental series do not identify an offending antigen, patients may be patch tested with their own products. Some such commonly used panels are "Standard Footwear Series" or "Standard Cosmetic Series" or a combination of the above two, called "Indian Standard Series" are shown in Annexure.

F. Technique/ Procedure:

Allergens to be tested are placed in allergen chambers or wells, which are made up of aluminium or plastic (as shown in Figure 1). The wells should be filled properly with the allergens, making sure that they come in contact with the skin. One test strip contains 10 such wells (Figure 2). Allergens are present in syringes in patrolatum or in liquid form (Figure 3). Once the allergens are placed in the wells, they are then carefully placed on the back of the patient (Figure 4) and then secured properly in place with adhesive tape (Figure 5). These strips can be applied to the thighs or arms. Test strips are applied from below upward. The outline of the strips is marked with a waterproof marker on the patient's skin. A proper record needs to be maintained about the sequence and the number of allergens applied to the back. Once the strips are secured on the back, the patient is advised to avoid bath for the next 7 days. He/she should not run, sweat, or scratch the back. The patient is also asked to wear loose, comfortable clothes and to sleep on his/ her sides and not on their back. Occulusion is removed after 48 hours, and 1st reading is taken (Figure 6). Then, subsequent readings are taken at 72 or 96 hours, and the final reading is taken on the 7th day from the day of application.

G. Grading of Reaction:

Depending on the erythema, induration, and blistering, the positive reactions are graded as:

- 0 Negative reaction
- + Mild reaction- erythema & possibly papules
- ++ Moderate reaction- vesicles
- +++ Severe reaction- bullous lesions

If a positive reaction at 48 hours becomes negative at 96 hours, it suggests local irritation and not ACD.



Figure 1: Test strip with allergen chambers



Figure 2: Test strip with 10 wells



Figure 3: Allergens present in syringes



Figure 4: Allergen strips placed on the back of a patient



Figure 5: Allergen strips secured on the back of a patient with adhesive tape



Figure 6: Occlusion removed after 48 hours

III. PITFALLS IN PATCH TESTING:

False positive:

Many times, there is irritant contact dermatitis to the adhesive tape, which is used to occlude the allergen wells. In such cases, the centre of the well, where the allergen was placed, shows no reaction.

Sometimes, false positive results can also be seen due to the pressure effect. The patient should be advised to stay in a comfortable environment. If there is excessive heat, then it might facilitate the penetration of the allergen and give a false positive reaction.

False negative:

If the concentration of the allergen applied to the skin is not sufficient, or the contact of the allergen with the skin is not correct, or while applying the wells on the skin, the allergen gets displaced, or a wrong allergen is chosen, then all these might give false negative reactions.

Late positive:

Many allergens can show late positive reactions, especially if they have low penetrance in the skin or have long persistence on the skin. So the final reading is given only on the 7th day.

IV. ADVERSE REACTION TO PATCH TESTING

- Active sensitization A negative reaction is followed by a late positive reaction after 10 to 20 days.
- "Angry back" or "excites skin syndrome." A few strong positive reactions cause a chain of multiple reactions to other patch tests that would otherwise be negative.
- Flare of dermatitis Usually, it is not serious and helps to validate the positive reaction.
- Adhesive tape reaction Rare with the current acrylate-based adhesive tapes.
- Koebner phenomenon Can be seen in patients with active psoriasis and lichen planus.
- Persistence of positive reaction Encountered more often with gold.
- Pigmentary alteration This includes post-inflammatory hyper- and hypopigmentation.
- Pressure effect Imprint caused by pressure from the chamber or when testing a solid material.
- Bacterial and viral infections Higher risk (bacterial) when testing plant substances.
- Necrosis/scar/keloid Risk of testing on unknown caustic substances that burn a hole in the skin.
- Sarcoidal reaction Has been described with metals, including palladium.
- Milia
- Anaphylactoid Extremely rare but potential risk with bacitracin, neomycin, and contact urticaria.

V. Interpretation & Clinical Correlation

- Always correlate test results with clinical history and distribution of dermatitis
- Final interpretation should guide strict avoidance of identified allergens
- Provide patients with detailed allergen-avoidance counseling

VI. Practical Algorithm for Patch Testing

Clinical suspicion of ACD → Detailed history & exam

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Exclude contraindications → Select appropriate allergen panel

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Apply strips (48h occlusion) → Sequential readings (48h, 72/96h, Day 7)
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Grade reaction (0 to +++) → Correlate with clinical relevance
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Confirm diagnosis → Educate patient on allergen avoidance
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SUMMARY:

Patch testing is essential investigation to identify specific allergens in allergic contact dermatitis (ACD). Contact dermatitis cases are on the rise due to the increasing use of cosmetics and industrialization. Detailed history and examination, followed by a proper patch test with standardized allergens will help in diagnosing the cases of allergic contact dermatitis. The final reading of patch test should always be taken on the 7th day and the result should be correlated with the history. Improper testing conditions and interpretation, might lead to many false positive and false negative reports. Once the diagnosis is confirmed, patient needs to be counselled to strictly avoid that ingredient in all the products which he/ she will be using in future.

ANNEXURE

Standard footwear series includes the following allergens

Sr. No.	Patch Test Allergen
1	Formaldehyde
2	Mercaptobenzathiazole
3	Potassium dichromate
4	Nickel sulphate
5	Colophony
6	Epoxy resins
7	Neomycin sulphate
8	Hydroxyquinone
9	Thiuram mix
10	Black rubber
11	Gluteraldehyde
12	Dioctyl phthalate
13	Disperse orange
14	Disperse blue
15	Kathon CG

Standard cosmetic & fragrance series includes the following allergens

Sr. No.	Patch test allergen
1	Vaseline (Control)
2	Ehylenediamine
3	Benzyl alcohol
4	Benzyl salicylate
5	Bronopol
6	Butyl Hydroxyanisole (BHA)
7	Butyl Hydroxytoluene (BHT)
8	Cetyl alcohol
9	Chloroacetamide

10	Geranium oil
11	2-hydroxy-4-methyl benzotriazole
12	2-hydroxy-5-methyl benzotriazole
13	Imidazolidinyiure (Germall 115)
14	Isopropyl myristate
15	Jasmine absolute
16	Lavender absolute
17	Musk Mix
18	Phenyl Salicylate
19	Polyoxyethylenesoleate (Tween 80)
20	Rose oil
21	Sorbitan sesquito (Arlacel 80)
22	Thiomersal
23	Triclosan
24	Triethanolamine
25	Vanillin
26	Cetrimide
27	Hexamine
28	Chlorhexidine Digluconate
29	Dizzolidnylurea (Germall II)
30	Propylene glycol
31	Kathon CG
32	Sorbic acid

Indian Standard series includes the following allergens:

Sr. No.	Patch test allergen
1	Vaseline (Control)
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2	Perubalsam
3	Mercaptobenzothiazole
4	Potassium dichromate
5	Nickel sulphate
6	Cobalt sulphate
7	Colophony
8	Epoxy resins
9	Parabens mix
10	Paraphenylenediamine
11	Parthenium
12	Neomycin sulphate
13	Benzocaine
14	Wool alcohols
15	Chlorocresol
16	Fragrance Mix
17	Thiuram Mix
18	Formaldehyde
19	Nitrofurazone
20	Black rubber Mix

SUGGESTED READING:

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