

## Guideline

## Patch testing with contact allergens

### Guideline of the German Dermatologic Society (Deutsche Dermatologische Gesellschaft, DDG) and the German Society for Allergy and Clinical Immunology (Deutsche Gesellschaft für Allergie und klinische Immunologie, DGAKI)

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#### 1 Introduction

One-year prevalence of contact dermatitis in the general population is 7%. 15 to 20% of the general population are sensitized to one of the common allergens [1, 2]. Contact dermatitis is the subject of a current guideline of the German Dermatologic Society (Deutsche Dermatologische Gesellschaft, DDG) [3]. The patch test is the only instrument suitable for routine diagnostics to prove sensitization to a substance causing an allergic contact dermatitis. Synchronous reproducibility ranges from 60 to 90 %, depending on test method and allergen [4, 5].

The contribution of patch testing to diagnostics, course of the disease and quality of life has been confirmed repeatedly [6–9]. On the whole, sick leave declines significantly after patch testing [10] (review articles on patch testing: [11–13]).

This guideline is targeted at physicians with training in allergology, entrusted with diagnostics in patients with past or present dermatitis or with providing an expert opinion (see also paragraph 2: indication). It is based on current scientific knowledge as presented in compendia and monographs [3, 14, 15], with consideration of the expertise of the German Contact Dermatitis Research Group (Deutsche Kontaktallergie-Gruppe, DKG) and articles concerning patch testing indexed in a special literature database

[16]. This guideline does not cover diagnostics of photoallergic reactions, for which separate recommendations exist [17, 18].

This guideline intends to ensure patch testing according to uniform criteria, improve quality and allow comparison of patch test results. Structure and objectives of this guideline are oriented towards recommendations of the German Medical Association (Bundesärztekammer) and the National Association of Statutory Health Insurance Physicians (Kassenärztliche Bundesvereinigung) [19, also see 20–22]. It was developed by DKG members, discussed in the full assembly of the DKG on November 14, 1998, in Munich in a consensus conference, and again approved by the executive committee of the DKG after revision on May 4, 2007. An algorithm schematically summarizing this guideline is depicted in Figure 1.

#### 2 Indication for patch testing

Patch testing is usually indicated if a contact allergic reaction of the skin or the adjacent mucous membranes is suspected, after the acute phase has cleared; to investigate suspected allergic occupational skin disease, especially when providing an expert opinion; in etiological or nosological unclear dermatitis to rule out delayed-type allergy (e.g. “hematogenic contact dermatitis”);

if provocation or exacerbation of a pre-existing skin disease is suspected (e.g. in all forms of dermatitis, particularly atopic dermatitis, or in psoriasis), as well as in the work-up of possibly drug-induced exanthema.

**Limitations:** Patch testing should not be performed in the presence of circumstances that can hamper the results. These are, for example, acute dermatitis, intensive UV exposure or long-term pre-treatment with topical corticosteroids. Immunosuppressive or immunomodulating drugs, such as glucocorticoids or ciclosporine, may adulterate patch test results [12]. Patch testing is not suitable to predict allergic contact dermatitis (in the sense of “prophetic testing”). But it can be useful in determining tolerated substances (e.g. cosmetic ingredients) when sensitization already has been diagnosed [11]. It does not serve to investigate the cause of symptoms that do not affect the skin but manifest as unspecific complaints.

Patch testing should not be performed during pregnancy. Hormonal effects on the test result are discussed. Furthermore, permeation of the allergens in a systemic effective dose and – even if not observed as yet – possible teratogenic effects cannot be excluded.

In determining the indication and in performing a patch test the risks of

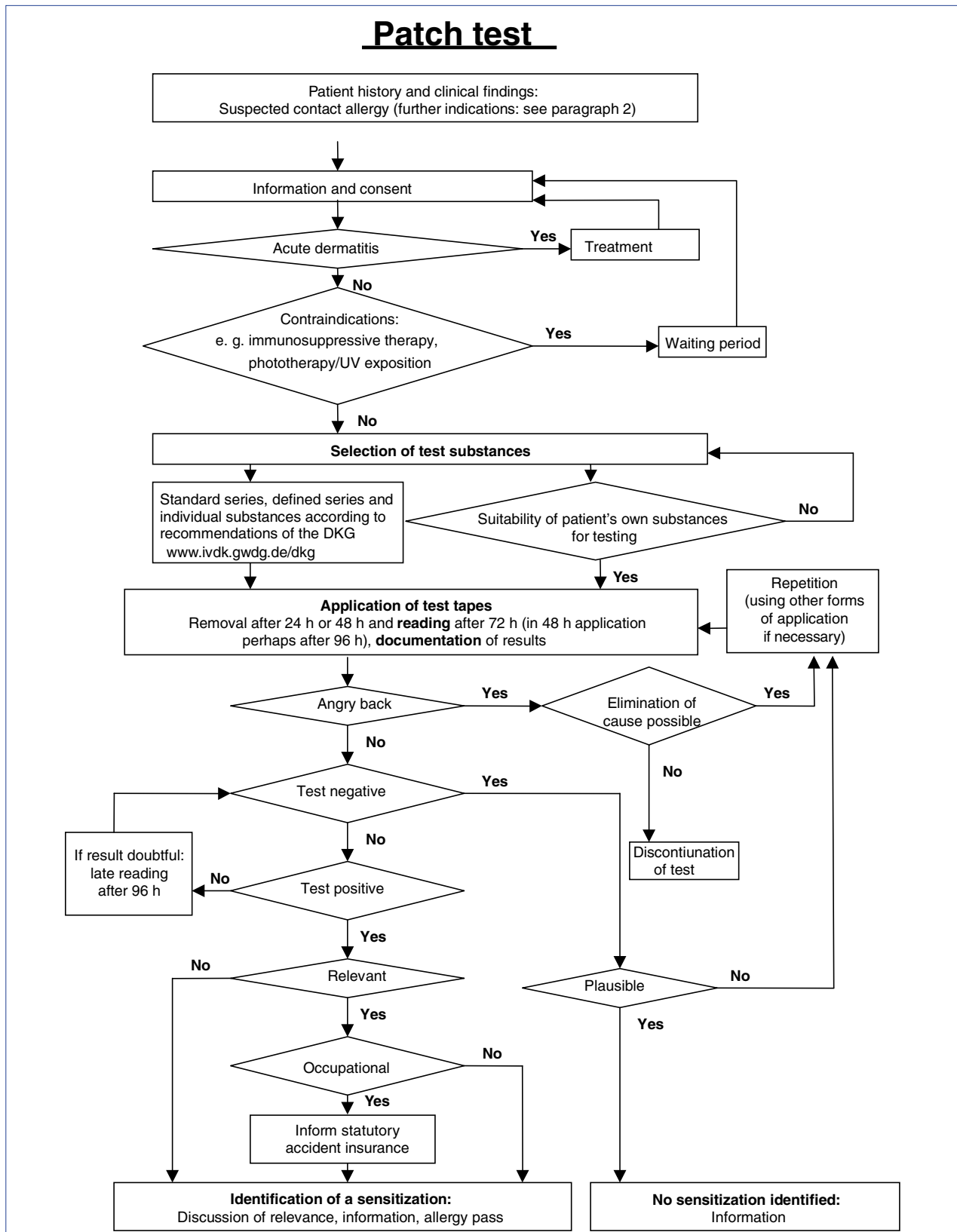


Figure 1: Algorithm of patch testing.

unwanted effects, such as e.g. iatrogenic sensitization or a relapse of dermatitis (“flare-up”) must be taken into consideration [12, 13]. If test results are

doubtful (see 3.3) the test can be repeated, however not before complete resolution of all reactions of the first test. Based on clinical experience, an interval of

about 2 months should be sought. Repeated patch testing with allergens, to which sensitization has definitively been demonstrated, should be avoided.

### 3 Technical details of the method

#### 3.1 Selection and application of the test substances

Generally, selection of allergens for patch testing should be guided by the patients' history and exposure. The standard series, however, should be patch tested independently of the individual history. This recommendation is based on the observation that, with this series, frequently sensitizations are detected despite a negative history. It is recommended to use galenically tested allergen preparations, which are approved as drugs, according to the standard series of the DKG (see DKG homepage: [www.ivdk.gwdg.de/dkg](http://www.ivdk.gwdg.de/dkg)), the European Society of Contact Dermatitis (ESCD) [23] and the ICDRG (International Contact Dermatitis Research Group) [24]. Adapting the standard series to local peculiarities is necessary occasionally [25]. In addition to the standard series, allergens to which the patient may have had contact should be tested. For this purpose, special test series defined by the DKG and/or individual allergens obtained from a commercial allergen catalogue should be used. Additionally, it may be necessary to patch test with substances or products brought in by the patient ("patient's own material"), if the respective allergens are not commercially available as patch test preparations. Patch testing with patients' own material requires special precautions which are not the subject of this guideline [26, 27]. Testing substances or mixtures of unknown chemical identity or unknown biological effects must be rejected.

Impeccable quality of the test preparations at the time of use has to be ensured by appropriate measures (cool storage, protection from light, storage in closed containers, respecting expiry date).

Commercially available products which are standardized and adequately clinically tested are recommended as application systems. It must be ensured that a sufficient amount of the test preparation is firmly applied to the skin during patch test exposure time.

In order to assess skin irritability at the time of patch testing, the obligatory irritant sodium lauryl sulfate (0.25% aqueous solution) can be applied simultaneously [28]. Erythema after 24 to 48 hours of occlusive application indicates a nonspecifically increased skin sensitivity. As a consequence, erythematous or

**Table 1:** Scoring of patch test reactions according to ICDRG recommendations [32].

Symbol	Morphology	Interpretation
-	No reaction	Negative
?	Erythema only, no infiltration	Doubtful reaction
+	Erythema, infiltration, possibly discrete papules	Weak positive reaction
++	Erythema, infiltration, papules, vesicles	Strong positive reaction
+++	Erythema, infiltration, confluent vesicles	Extreme positive reaction
ir	Different types of reactions (soap effect, vesicles, blister, necrosis)	Irritant reaction
nt		Not tested

Note: Follicular reactions can be denoted with the symbol "f". They can be categorized as doubtful reactions.

weak positive patch test reactions to contact allergens with an inherent irritant potential should be interpreted as allergic with caution [29] (for difference between reading and interpretation, see paragraph 3.3).

#### 3.2 Time of application, test area and duration of exposure

Dermatitis should have cleared at the time of patch testing. The test area may not be pre-treated and must be free of any pathologic findings. Usually, the test area is the back with a distance of 2–4 cm from the centre line. If, in exceptional cases, patch testing must be performed in other skin areas, the test site should be noted. Allergen exposure time should be 24 or 48 hours. There is no proof for a general superiority of one of these two exposure times [30].

#### 3.3 Reading and interpreting the test reaction

Test reactions should be evaluated allergologically not before 30 minutes after removal of the patches. Reading the test is obligatory after removal of the patches, as well as 72 hours after application when the test was applied for 24 h, and 72 (or 96) hours after application when the test was applied for 48 h. Additionally, late readings are recommended, particularly if test reactions cannot definitely be classified as allergic or irritant, or if sensitization to allergens is

suspected which often elicit reactions later than after 72 hours (e.g. aminoglycoside antibiotics, glucocorticoids) [31]. The premature completion of the patch test by the physician at the reading 48 hours after application of the test is emphatically rejected due to resulting false judgements [31]. Reaction evaluation is based on morphology [32] (Table 1).

Usually, reactions rated "+", "++" or "+++" at 72 hours or later are interpreted as "allergic". The time course of the reaction may influence interpretation [12, 33]. A "crescendo" or "plateau" pattern suggests an allergic type, a "decrecendo" pattern rather an irritant type. In late reactions appearing not before 10–14 days after application of the patch test, a ("iatrogenic") sensitization by the patch test has to be considered. Positive reactions to structurally related substances may reflect cross-reactions. If many (> 5) positive reactions to chemically unrelated substances occur, this "polysensitization" may denote an individually increased susceptibility for contact allergy [34, 35]. However, if multiple "positive" reactions occur, an "angry back / excited skin syndrome" must be considered [36]. In this case, many of the morphologically positive (+ to +++) reactions must be interpreted as "false-positive". If, in spite of an explicit patient history, no allergic patch test reaction to a suspected allergen is elicited, a "false-negative" reaction must be

taken into consideration. This may be due to the test method (too low allergen concentration, inappropriate vehicle, insufficient occlusion, too short reading period) or due to reduced immunoreactivity of the patient (e.g. due to topical or systemic medications or UV light). In the case of false-positive reactions, e.g. in the "excited skin syndrome", or if false-negative reactions are suspected, a patch test with the individual substances concerned should be repeated at a later time, however not before 2 months later, if possible. Further methods such as use tests (e.g. ROAT [37, 38]) may help to investigate the suspected sensitization, if performed by experienced investigators.

#### 4 Relevance

Clinical relevance of each test reaction interpreted as allergic must be evaluated. A sensitization is clinically relevant if the skin disease was elicited by contact with the allergen. If the disease was definitely elicited by another cause, no relevance can be attributed to the respective allergen. The intensity of the test reaction (++/+++ [39] or a positive use test [40] may point towards clinical relevance. Reactions with (still) unclear relevance might gain significance later, e.g. after new information on allergen exposure. Criteria to evaluate relevance are presented in [12, 41–43].

#### 5 History and patient information

Before patch testing, a physician with training in allergology has to take the patients' history and examine the patients' skin with regard to its suitability of being tested. Patch testing without a patient history taken by a physician must be rejected. History must at least include information on atopy, occupation and possible allergen exposure. History auxiliaries may be helpful in taking the patients' history, especially in cases of occupational dermatitis [44–47]. The individual test program has to be compiled according to the patient's history, possibly with reference to DKG recommendations [48–53] (also see DKG homepage: [www.ivdk.gwdg.de/dkg](http://www.ivdk.gwdg.de/dkg)). Before testing, each patient must be informed about purpose, procedure and the side effects [11, 12] of patch testing as well as about data privacy laws. Patient's consent to performing the test and further data utilization must be obtained. A DKG recommendation for information and a

consent form are available on the DKG homepage ([www.ivdk.gwdg.de/dkg](http://www.ivdk.gwdg.de/dkg)). After patch testing, the results have to be discussed with the patient with special emphasis on certain, doubtful or missing relevance as well as the significance of conspicuous (e.g. irritant) test sites.

#### 6 Documentation and completion of the test

Written documentation must include information on patient's history, indication for testing, test method (tapes, test chambers), test preparations (allergens, vehicles, concentrations), test reactions including their time course, relevance assessment, and dermatological diagnosis. The fact that the patient was informed before and after testing must be noted. Allergens which elicited unambiguous allergic reactions should be listed in the allergy pass. Weak positive reactions ("+") to test preparations, which also often elicit irritant reactions, and for which no relevance could be determined, should be evaluated very critically in this context [54]. If such allergens are listed in the allergy pass, a qualifying evaluation should be given. Clinical relevance of allergic reactions should be noted. Patch testing is completed by giving a final dermatological diagnosis and details of the sensitizations diagnosed.

#### Procedure in creating consensus

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