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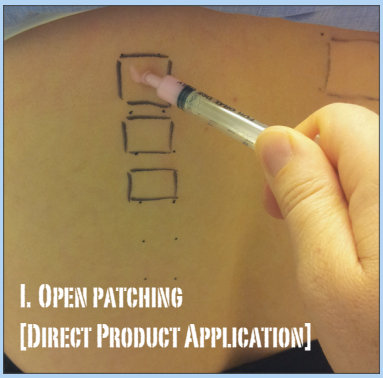
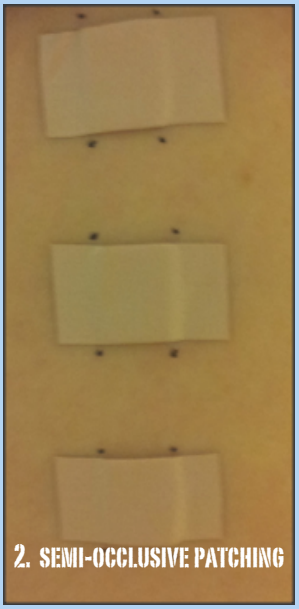
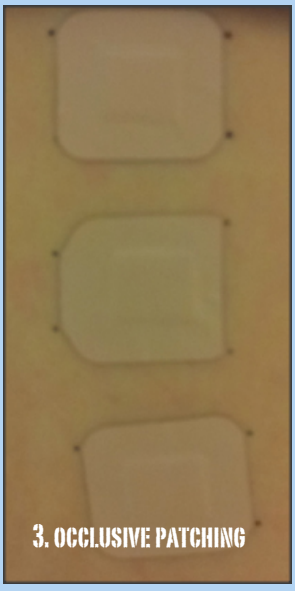
Human Repeat Insult Patch Test

STEPS







The most common procedure for Screening for Skin Safety

Supportable Claims

- Non-primary Irritation
- Non-primary Sensitisation
- Suitable for Sensitive Skin
- Dermatologist Certification

Induction Phase

A small sample of the product is applied to the target area of the back. For semi-occlusive or occlusive patching, hypoallergenic patches are applied over the product. The patch is removed after 24 hrs, and the skin responses are read after 48 hrs. This sequence is repeated nine times, applying product to the exact same area. Any visible irritation is recorded.

Challenge Phase

After a rest period of 10 to 21 days, a patch is applied to a different area in order to challenge for sensitisation.

3 Levels of Challenge

Open Patching (no cover)
Semi-occlusive Patching- 2 sides open
Closed Patching- 4 sides sealed

Product Concentration

Leave on products - these are applied “neat”.
Wash-off Products - usually diluted 1:10 , but other dilutions may apply, according to intended use and likely skin contact.

Validity

Data for at least 50 test subjects is accumulated. All 500 patches should show a negative skin response.

Sensitive Test Panel

The proportion of self nominated sensitive skin types in the general population is around 15 to 25%. Approximately twice this number are inducted into the test panel, so that at least 25 of each panel of 50 are self nominated sensitive skin type.

Dermatologist Certification

This type of study is suited to certification by a qualified Dermatologist.

References

1. **Dermatoxicology Methods** *Marzulli F., Maibach H. Published Taylor & Francis 1 Fith Edition 1997*

2. **A review of critical factors in the conduct and interpretation of the human repeat insult patch test** *McNamee P., et al* Regulatory Toxiciology and Pharmacology Vol 52: 2008

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Repeat Insult Patch Test (RIPT)
Sensitive (or Standard) Panel

Objective
to determine the irritation and/or sensitization potential of a test material(s), in support of sensitive skin claims, after repeated application under occlusive or semi-occlusive patches to the skin of human subjects. May provide supporting evidence for hypoallergenicity claims when in conjunction with an invasive test.

Subjects
Male & female, percentage(25 to 100%) of panel selected from subjects from the normal population, or who have self-nominated as sensitive skin types.
• Informed of the nature of the test including possible adverse reactions.
• Written informed consent documents signed by all participants prior to induction.
• Parental consent will be obtained from minors.
• Only subjects that are considered dependable and able to read, understand and follow directions will be requested to participate.
• Prior to initiation of a test, each subject will complete a medical history form. The subjects will not exhibit any physical or dermatological condition which would preclude application of the test material(s).

Induction Phase
a) The quantity of test material applied per test patch will be approximately 0.2mL or 0.2g of each substance.
b) Test material(s) will be placed on a 2cm square Parke-David Readi-Bandage (occlusive) or to a 2cm square of Webril nonwoven fabric affixed to Scanpor tape (semi-occlusive) or equivalent coverings. The patch(es) will be applied to the subject's back between the scapulae and waist, or to the inner forearm. Semi-occlusive tape will be used when evaluating known irritating and/or volatile materials.
c) The subjects remove the patches 24 hours after each application. 24 hour rest periods follow each removal. Prior to each reapplication, site(s) are evaluated by a trained staff member. This procedure is repeated until 9 applications of the test material(s) are made.
d) Skin responses are evaluated according to the following scale: 0 = no evidence of any effect
? = query [?] +/- = minimal, faint, uniform or spotty erythema.
1 = pink uniform erythema covering most or all of the contact site 2 = pink-red erythema visibly uniform in entire contact site.
3 = bright red erythema with or without petechiae or papules. 4 = deep red erythema with or without vesiculation or weeping.
Accompanied edema (swelling) at any test site is recorded with an "e" and is described as mild, moderate or severe compared with normal surface of surrounding skin.
e) if a subject develops a positive reaction of a 2 - level or greater during the induction phase, the patch is applied to a fresh adjacent site for the next application. If a 2 or greater reaction occurs at the second site or application, no further applications of the reactive test material are made for the remainder of the induction phase. However, reactive subjects will be subsequently patched with the test materials at a virgin test site during the scheduled challenge phase of the study.

Challenge Phase
a) Ten to 21 days after application of the final induction patch, challenge patch(es) are applied to previously unpatched (virgin) sites, adjacent to the original induction patch sites. The challenge sites are scored 24 to 48 hours after application. The subjects are asked to report any delayed reactions which might occur after the final challenge patch reading.

Reporting

The final report to sponsor of a study will include: purpose, test materials, panel selection and demographics, experimental design, results and conclusions. Results of dermal responses will be presented in tabular form.

Dermatologist Certification
This is available on request and an additional charge applies.

Test Material Information
A sufficient quantity of each test material should be submitted by the sponsor.
Please forward Per 50 subjects: liquids - approx. 250ml ; powders, semi-solids - approx 250g ; fabrics/ fibres - approx 600sq in)