

# ***Pre-Clinical Research Services, Inc.***

## **Dermal Pig Models**

PCRS does a couple dermal hypersensitivity models. They do a delayed type hypersensitivity model using di-nitro fluoro benzene (DNFB) to sensitize the pigs over a two week period and this is followed by a DNFB challenge. On the day of challenge they apply a small amount of DNFB to the skin in each square of a grid marked on the shaved skin on the back of the pig. Either before DNFB challenge or within the first 2 hours post-DNFB challenge each square of the grid receives an application of different dilutions of test article, no treatment or a positive control treatment such as clobetasol which is known to block the DTH response.

At 24 and again at 48 hours after the DNFB challenge they score each square of the grid and photograph the back of each animal. Then following the 48 hour scoring and photographs they euthanize the pig and collect a biopsy from each grid square and that is fixed in formalin and sent to Alison Bendele for histopathology evaluation.

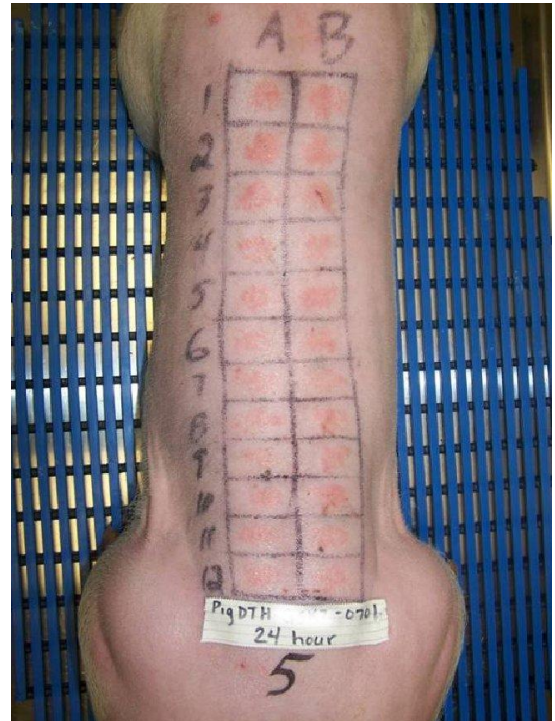
The clinical scoring of each grid square uses the following criteria:

- Intensity of Erythema
- Extent of Erythema
- Induration

The histopathology evaluates epidermal and dermal inflammation using a scoring system to determine the intensity of this inflammation.

The photo to the right shows a typical grid on the back of a pig at 24 hours post-DNFB challenge.

Another pig dermal model they have done is a pharmacokinetics study following topical application of test article. Test article is applied to an area of skin, typically 25% of body surface area, and blood samples are collected pre-dose and up to 12 post-dose time points through 48 or 72 hours. They have also done a dermal absorption study where they apply test article to the skin over a knee joint and collect pre and post-dose blood samples and at time points post-dose they euthanize the pigs and collect synovial fluid, joint cartilage (meniscus or articular cartilage) and synovial tissue that is frozen and later assayed for test article concentration.



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