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Simplifying Progress

Epi2SensA Assay on the EpiDerm™ Reconstructed Human Epidermis (RhE)

Regulatory-Ready, Validated, Model for Non-Animal Skin Sensitization Testing

Overview

A new multi-laboratory validation study has demonstrated that the Epi2SensA assay, run on EpiDerm™ reconstructed human epidermis (RhE), delivers reliable assessment of skin sensitization potential, validated for regulatory acceptance. The work was conducted in four independent laboratories using 20 blinded reference chemicals and following OECD validation principles.

The method evaluates changes in a defined panel of genes associated with skin sensitization after topical exposure of EpiDerm tissues. The protocol and decision criteria were optimized for EpiDerm and shown to perform consistently across laboratories and chemical classes.

Why It Matters for You

- **Regulatory alignment**: Epi2SensA is proposed for integration into OECD Test Guideline 442D as an additional RhE-based skin sensitization method, supporting regulatory acceptance of non-animal approaches.
- **Human-relevant biology:** EpiDerm RhE mimics key structural and metabolic features of human epidermis, improving mechanistic relevance versus traditional animal tests.
- **Challenging substances:** The assay has been shown to be suitable for hydrophobic compounds and substances requiring metabolic activation (pre/pro-haptens), which are often difficult to evaluate with simpler *in vitro* systems.
- **Robust and transferable:** High inter- and intra-laboratory reproducibility demonstrates that the method can be reliably implemented across sites, supporting global deployment in industry and contract labs.

What This Enables

By combining a well-characterized RhE platform (EpiDerm) with a rigorously validated gene expression-based assay (Epi2SensA), you gain a powerful, non-animal tool for skin sensitization hazard identification that is aligned with current and emerging regulatory expectations.

Application Areas

Safety and Tolerance assessment of ingredients and formulations in pharmaceuticals, cosmetics, personal care products, chemicals and household products.

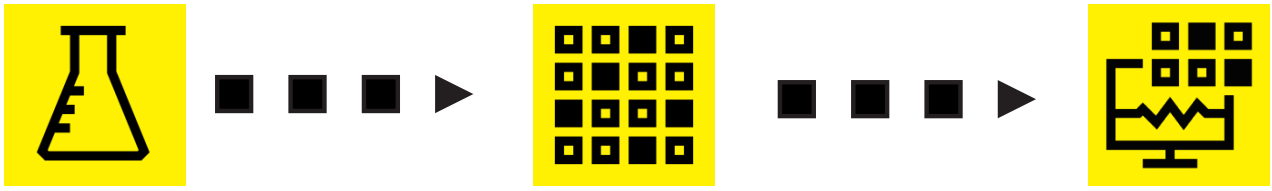
Enablement of Next-Generation Risk Assessment (NGRA) and Integrated Approaches to Testing and Assessment (IATA)

Supports reduction and replacement of animal-based sensitization tests within corporate 3R and non-animal testing strategies

Key Results:

- Accuracy: 88.3%
- Sensitivity: 88.1%
- Specificity: 88.9%
- Reproducibility:
  - Inter-laboratory: 83.3%
  - Intra-laboratory: 85%

Workflow



1. Test Chemicals

Find the highest concentration of the test chemical that can dissolve in the chosen solvent.

2. Dose-Finding Study

Using an LDH (lactic dehydrogenase) assay, test a range of concentrations to determine which levels begin to show cytotoxic effects.

3. Main Study & Results

Select the non-toxic concentrations for the main experiment, and measure the skin-sensitization gene expression profile via RT-qPCR.

Figure 1. Overview of the Epi2SensA method.

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Get in Touch:

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