IN VITRO SKIN SENSITIZATION TEST

GARD™skin—200 genomic biomarkers

[OECD TGP 4.106]

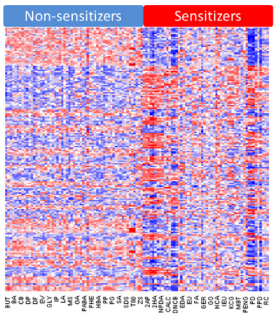
The GARD technology platform

GARD – Genomic Allergen Rapid Detection – is a highly versatile genomic-based *in vitro* testing platform for assessment of various toxicological endpoints. GARD makes use of unique genomic biomarker signatures comprising genes involved in pathways known to be relevant to the toxicological outcome. Using the latest pattern recognition technology, the large volume of informational content provided by this approach enables mechanism-of-action based decisions, resulting in consistently high predictive accuracy.

GARD™skin provides a robust solution to the demands for 3Rs by generating reliable outcomes via *in vitro* testing using a relevant human cell line (SenzaCell™).

Why is GARD™skin the most accurate assay on the market?

The 200 genes in GARD™skin are well-characterized and describe many diverse processes associated with skin sensitization. In contrast to the limited mechanistic information obtained from single biomarkers, the large informational content of this approach provides a more holistic view of the immunological response to skin sensitizing chemicals, which is reflected in its high predictive accuracy.



The genomic biomarker signature in GARD™skin covers several mechanistic events of sensitization.

How to GARD your products in six steps:

1. **GARD Input Finder:** Dose-response to find the GARD input concentration where 90% of SenzaCells™ survive.
2. **GARD Main Stimulation:** SenzaCells™ are exposed at the GARD input concentration.
3. **RNA extraction:** Following 24h of cellular stimulation, total RNA is isolated using an RNA extraction kit.
4. **Gene expression profiling:** Gene expression of the 200 genes in the biomarker signature is measured using NanoString.
5. **GARD data analysis application:** The resulting gene expression is analysed by pattern recognition, using a machine learning algorithm based on a fixed set of reference samples
6. **Results:** Report provided on test substance classification as sensitizer or non-sensitizer.

AT A GLANCE

Tox Endpoint: Specific identification of skin sensitizing chemicals.

Parameters: Genomic readout of 200 genes relevant to sensitization.

Why: Develop safer products based on human relevant data supporting the principles of 3R.

How: State-of-the-art machine learning tools used to develop the model. Transparent classification; no subjective judgement required.

Performance: Accuracy 94%, false positives 7% and false negatives typically 4%.*

Compliant: OECD TGP 4.106 and accepted by ECHA for REACH dossiers.

Turnaround time: 4-6 weeks

Sample requirements: 0.5 g (solids) or 1 ml (liquids). Can be adapted to lower amounts.

GARD™skin FOR REACH DOSSIERS

The REACH Regulation allows the use of non-adopted *in vitro* methods in case they meet the EURL ECVAM criteria for entering pre-validation. For the GARD™ assay this criterium is met.
ECHA

ABOUT SENZAGEN

SenzaGen is dedicated to the development of innovative *in vitro* methods for safety testing of various toxicological endpoints across different industries. SenzaGen performs GARD™ in its own laboratory and through CRO partners around the world.