GARD®skin

OECD TG 442E: *in vitro* skin sensitization

Approved by OECD for regulatory testing
As a new method included in OECD TG 442E for *in vitro* skin sensitization, GARDskin supports discrimination of skin sensitizers and non-sensitizers in accordance with the UN GHS.

Your stand-alone test for product development
With demonstrated high performance and broad applicability, GARDskin is appreciated across industries as a stand-alone product development *in vitro* tool for skin sensitization hazard assessment.

Based on your needs within *in vitro* skin sensitization, GARDskin Dose-Response is available as a test option for quantitative potency assessment, predicting the point-of-departure concentration.

Do you have "diffcult-to-test" samples?

GARDskin works for a wide variety of test chemicals, with demonstrated applicability to evaluate "difficult-to-test" samples, including:

- Complex mixtures
- Indirectly acting haptens
- Lipophilic compounds
- Metal and metal salts
- Solid materials
- Surfactants

Features and Benefits

Test system
- Human dendritic-like cell line: SenzaCell™.

Solvent
- Standard: DMSO and H_2O.
- Other available solvents: Acetone, DMF, Isopropanol, Ethanol, Glycerol, Olive oil, Sesame oil.

What it measures
- Gene expression profile of 200 genomic biomarkers.

Readout
- Binary prediction: Skin sensitizer or non-sensitizer.

Compliance
- OECD TG 442E, GLP or non-GLP.

Short turnaround time
- 4-6 weeks for standard studies.

Low sample requirement
- 0.5g (solid) or 1ml (liquid).

High performance
- 94% accuracy, 93% sensitivity and 96% specificity for skin sensitizing hazard prediction.*

Additional services (optional)
- GARD®skin Medicla Device for assessment of solid materials.
- GARD®skin Dose-Response for predicting the point-of-departure concentration.

How GARD® works

GARDskin uses a human dendritic-like cell line, SenzaCell™, which mimics a critical part of the human immune system and is able to recognize allergens.

In each test case, the cells are exposed to the test sample after which genomic biomarker signature is measured. The gene expression pattern of the exposed cells is then compared to existing patterns induced by well-known chemicals and analysed by pattern recognition and machine-learning technology.

As a result, the test sample is classified as a sensitizer or non-sensitizer.

All the GARD assays are based on the same technology platform. Read more about the GARD technology platform and assay development principles on www.senzagen.com/science.

Validation study

Method

A formal validation study for GARDskin was performed at three independent laboratories in compliance with the OECD guideline.

A total of 28 test substances were tested blindly using GARDskin and classified into sensitizers or non-sensitizers.

Results

The study results showed high reproducibility as well as outstanding predictive performance.*

Table 1. The GARDskin validation study results demonstrated high reproducibility as well as outstanding predictive performance.

Accuracy	94%
Sensitivity	93%
Specificity	96%
Within Laboratory Reproducibility	82-89%
Between Laboratory Reproducibility	92%

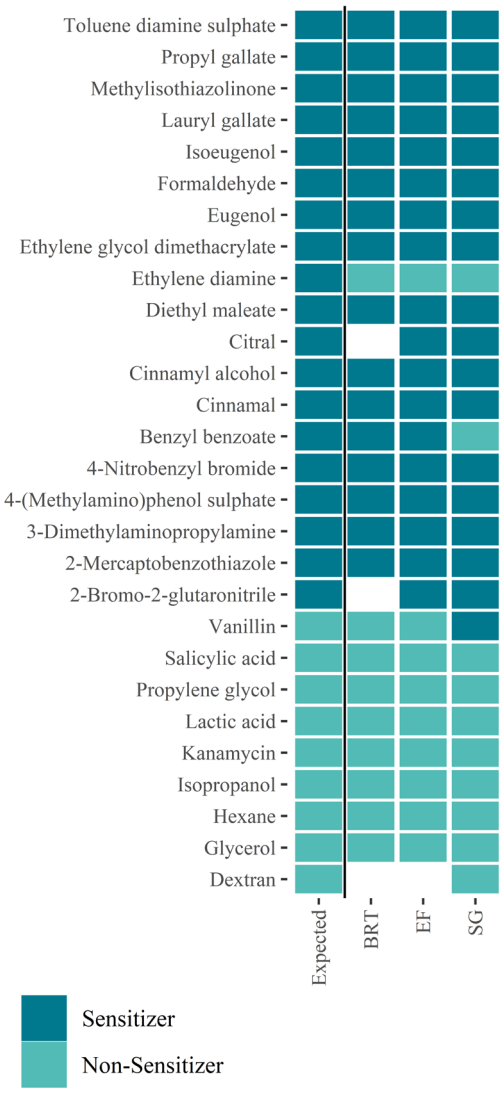

Figure 1. The GARDskin validation study results from three independent laboratories.

GLP compliant laboratories

SenzaGen's laboratory in Lund is accredited by the Swedish national accreditation body, SWEDAC, for the conduct of *in vitro* toxicity studies with cell systems in compliance with Good Laboratory Practice (GLP).

GARD is also available at selected CRO partners in compliance with GLP.

*Johansson et al., Validation of the GARDskin assay for assessment of chemical skin sensitizers – ring trial results of predictive performance and reproducibility. Toxicological Sciences. May 17, 2019.