GARD™skin

Skin sensitizing hazard prediction with high accuracy and broad applicability

GARDskin is a robust *in vitro* test to identify potential chemical skin sensitizers with broad applicability and over 90% prediction accuracy.

The test provides a binary prediction, classifying the test sample into either a skin sensitizer or non-sensitizer.

Over 500 samples have been successfully tested in GARDskin at SenzaGen's lab. Many of them are considered "difficult-to-test" with traditional *in vitro* methods. For example:

- Complex mixtures
- Pre- and pro- haptens
- Surfactants

Demonstrated applicability to Difficult-to-Test samples

Features and Benefits

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

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.

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

Short turnaround time
- Test time: 2 weeks.
- Final report: Additional 2-4 weeks.**

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

Compliance
- GARDskin is included in the OECD Test Guideline Program (TGP 4.106). The ESAC has issued a positive opinion on the test method and recommends it be adopted as an OECD Test Guideline for skin sensitization.
- Depending on the regulatory context, positive results obtained with GARDskin may be used stand-alone to identify skin sensitizers. Furthermore, the ESAC considers that GARDskin is a functional and valid test method ready for use in industrial screening applications.

*Johansson H. et al. Validation of the GARDskin assay for assessment of chemical skin sensitizers – ring trial results of predictive performance and reproducibility. Toxicological Sciences. 2019.
** For non-GLP studies.

How it works

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

In each test case, SenzaCells 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.

The study results are presented in Figure 1 with key performance statistics summarized in Table 1.

More information

The validation study results is published in a peer-reviewed article.*

A full report of the study has been submitted to EURL ECVAM for scientific review.

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

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

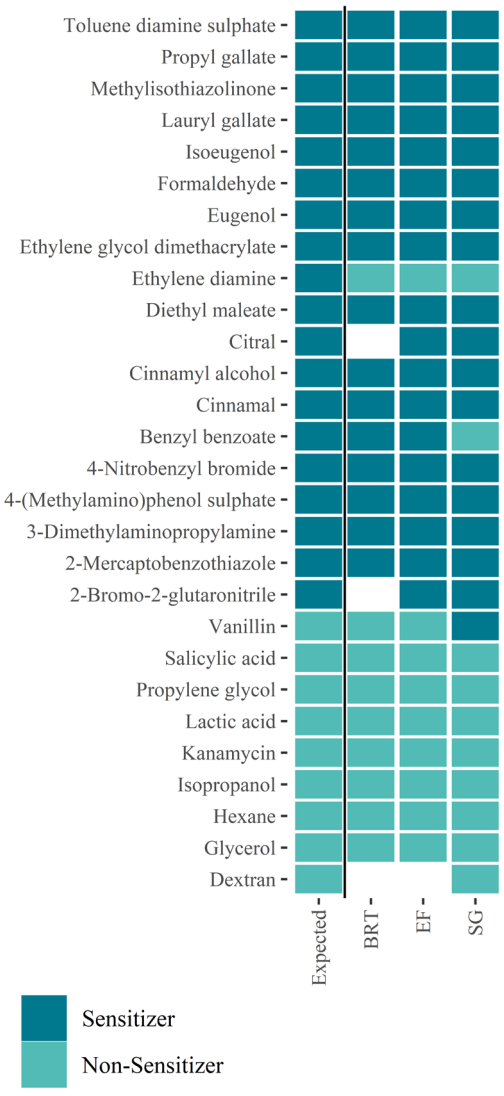

Figure 1. The GARDskin validation study results from three independent laboratories.

*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.