GARD®skin

OECD TG 442E, TG 497
in vitro skin sensitization

Full regulatory compliance
GARDskin is included in the OECD Test Guideline (TG) 442E for *in vitro* skin sensitization and is approved for addressing the Key Event 3 (KE3) of the Adverse Outcome Pathway (AOP) for skin sensitization. It is also included in OECD TG 497: Defined Approaches for Skin Sensitization (DASS), where it is part of two Defined Approaches (DAs):

- The "2 out of 3" DA for hazard identification.
- The Integrated Testing Strategy (ITS) for hazard identification and potency sub-categorization (1A, 1B, NC).

Bringing high performance and extended applicability to DASS
With demonstrated high performance and broad applicability to hydrophobic substances (Log P > 3.5) and other challenging chemical groups, GARDskin extends the overall applicability of DASS, helping to fill data gaps in regulatory skin sensitization testing.

Do you have "difficult-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
- Hydrophobic/lipophilic compounds
- Metal and metal salts
- Solid materials

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 196 genomic biomarkers.

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

Compliance
- OECD TG 442E, OECD TG 497, GLP or non-GLP.

Short turnaround time
- 4-8 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 Medical Device for assessment of solid materials.
- GARD®skin Dose-Response for quantitative potency assessment and safe dose levels.

*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.

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.

Your stand-alone test for product development

GARDskin analyses the expression of 196 biomarkers following exposure to potential skin sensitizers. Many of these biomarkers are well-established genes associated with different KEs in the AOP.*

By capturing a broad and mechanistically relevant gene signature, the assay offers a comprehensive view of the immunological response to potential skin sensitizers in humans. This rich dataset supports informed and reliable decision-making during product development. Learn more about the gene signature and mechanistic pathways.

* ESAC Opinion No. 2021-01, 8 July 2021. ESAC opinion on the scientific validity of the GARDskin and GARDpotency test methods.

One testing strategy for sensitizers—hazard, potency and PoD

Combining GARDskin with the GARDskin Dose-Response assay provides a tiered testing approach performed within a single test setup. It enables hazard identification, CLP-aligned potency sub-categorization, and point of departure (PoD) determination. This integrated approach saves time and cost while supporting more informed decision-making and potentially reducing the need for additional testing.

Bundle pricing available

Contact us for pricing details on the combined GARDskin and Dose-Response assays.

Discuss your testing needs: sales@senzagen.com

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.