GARD®skin Medical Device

In vitro skin sensitization testing for medical devices and solid materials

GARDskin Medical Device offers an *in vitro* alternative for skin sensitization testing as a part of the Biological Evaluation of Medical Devices according to ISO 10993.

As an adaptation of GARDskin (OECD TG 442E), the assay supports testing of extracts from Medical Devices and solid materials, classifying test items as skin sensitizers or non-sensitizers.

- Supports both polar and non-polar extraction vehicles (ISO 10993-12).
- Human-relevant with high predictive accuracy.
- Fully aligned with the 3Rs.

Powered by genomics and machine learning, the assay is human-relevant and highly accurate, enabling shorter turnaround times compared to traditional animal studies.

Final-stage ISO 10993-10 validation

Features and Benefits

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

Extraction vehicles
- Saline, Olive oil, Sesame oil, Cell culture media.

What it measures
- Gene expression profile of 196 genomic biomarkers.

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

High performance
- 94% accuracy for skin sensitizing hazard prediction.*

Short turnaround time
- 4-8 weeks for standard studies.
- Fast track available.

Low sample requirement
- 1 ml extracts from the test sample.

Compliance
- OECD Test Guideline 442E.
- ISO 10993-10: Listed in Annex C; final-stage ring trial validation ongoing toward full inclusion.
- GLP-compliant laboratory.

Additional service (optional)
- GARDskin Dose-Response for quantitative potency assessment.

*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.

Scientific expertise and personal support
Top reasons customers test with us

Preparing for the regulatory transition in skin sensitization testing

As ISO 10993-10 continues to evolve, the integration of New Approach Methodologies (NAMs) supports organizational readiness for updated regulatory expectations.

Early adoption may offer practical advantages, such as:

- Building internal NAM-relevant databases.
- Gaining hands-on experience interpreting NAM-based results.
- Strengthening weight-of-evidence in regulatory submissions.
- Reducing late-stage regulatory risks.
- Aligning with 3Rs principles and sustainability goals.

Typical use scenarios

From early material screening to regulatory submission, GARD® supports decision-making at multiple stages:

Product development

- Early screening of new materials.
- Comparative testing of material candidates.
- Pre-screening to reduce reliance on in vivo studies.

Manufacturing optimization

- Evaluating processing parameters.
- Assessing batch-to-batch variation.

Regulatory submission

- Supporting weight-of-evidence approaches.
- Strengthening documentation for low-risk material or manufacturing changes.
- Integration into structured testing strategies.

How GARD® works

GARDskin Medical Device is an adaptation of the GARDskin assay. The test uses a human dendritic-like cell line, SenzaCell®, which mimics a critical part of the human immune system and is able to recognize allergens.

For each test sample, prior to performing the standard GARDskin protocol, an additional extraction step is performed to prepare extracts from the test items (solid materials or final devices) according to ISO 10993-12.

The cells are then exposed to the extracts after which genomic biomarker signature is measured. The gene expression pattern of the exposed cells is compared to existing patterns induced by well-known chemicals and analyzed by pattern recognition and machine-learning technology. As a result, the test item is classified as a sensitizer or non-sensitizer.