GARD®air

A predictive test for chemical respiratory sensitizers

GARDair is an *in vitro* test capable of identifying chemical respiratory sensitizers.

The test provides a binary prediction, classifying the test samples as either respiratory sensitizers or non-sensitizers.

With a high specificity of 95%, GARDair is recommended for use as a product development tool to identify and rule out respiratory sensitizers in candidate ingredients.

The high specificity means that there are few false positive results (5%). If a sample is classified as a respiratory sensitizer in GARDair, you can trust the result and remove the candidate ingredient with confidence. Furthermore, unnecessary measures on falsely classified sensitizers can be avoided.

GARDair is the only available test for respiratory sensitization on the market.

For product development

Features and Benefits

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

Solvent
- DMSO and H_2O within standard protocols.

What it measures
- Gene expression profile of 28 genomic biomarkers.

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

Recommended use
- With 95% specificity, GARDair is recommended for use as an R&D tool to identify and rule out respiratory sensitizers in candidate ingredients.*

Short turnaround time
- 4-8 weeks for standard studies.

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

Compliance
- GLP or non-GLP.

How GARD® works

GARDair 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 respiratory 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.

Inter-laboratory ring trial

Method

A inter-laboratory ring trial was performed in three independent laboratory with blind assessment of 29 compounds, including expected respiratory sensitizers, skin sensitizers and non-sensitizers.

Results

The results suggest that GARDair is transferable and highly specific, which makes it an ideal R&D tool for identification and ruling out chemical respiratory sensitizers.

More information

The full study of the ring trial and the performance of GARDair is summarized in a poster*, which is available at www.senzagen.com/science/posters.

Table 1. The GARDair inter-laboratory ring trial results demonstrated high reproducibility as well as outstanding predictive performance.

Accuracy	74%
Sensitivity	53%
Specificity	95%
Within Laboratory Reproducibility	52-72%
Between Laboratory Reproducibility	79%

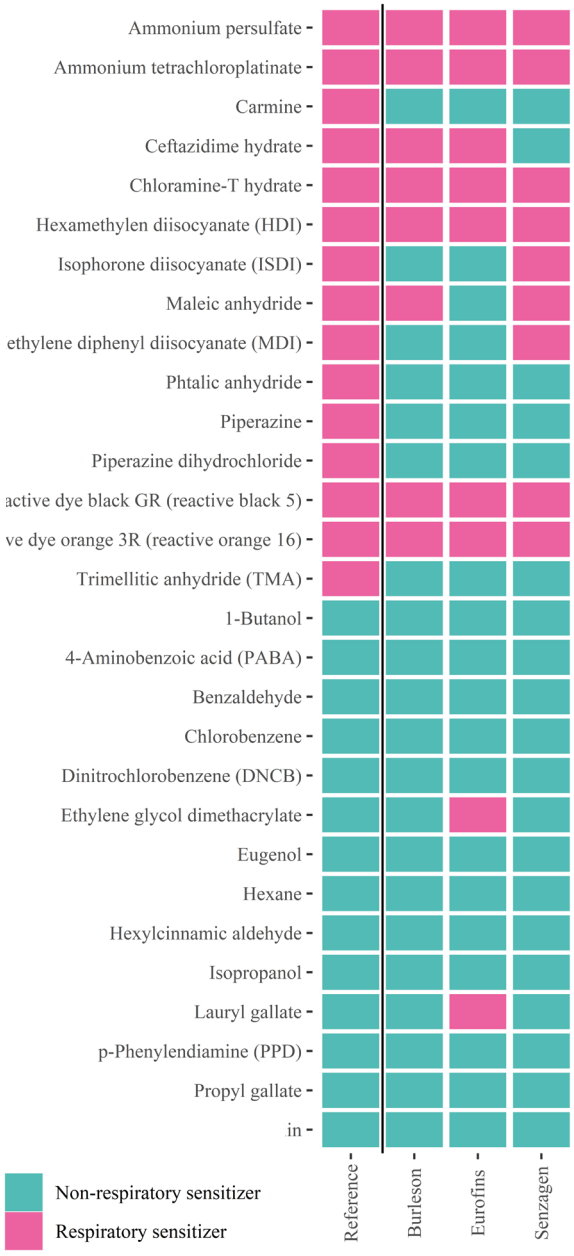

Figure 1. GARDair inter-laboratory ring trial results from three independent laboratories.

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.

*Forreryd et al., Inter-laboratory ring trial of the GARDair assay for assessment of respiratory sensitizers, Poster abstract accepted at SOT 2020.