

## GARD<sup>®</sup>air

*In vitro* hazard identification of respiratory sensitizers



Powered by genomics and machine learning, GARDair offers a non-animal solution for respiratory hazard assessment, supporting decision making in product development and safety assessment.

The assay provides a binary classification of test items as respiratory sensitizers or non-sensitizers. With 95% specificity, GARDair yields very few false positives, allowing efficient removal of sensitizing candidates and reducing unnecessary follow-up work.

GARDair supports respiratory safety assessments across chemicals, biotech, and pharmaceutical industries and is also suitable for evaluating hazards in occupational health and workplace safety contexts.

### Complementary potency assessment

For identified respiratory sensitizers, a dose-response extension of the standard protocol can be applied to generate quantitative potency information for downstream risk assessment and prioritization.

### Integrated testing strategies

GARDair can also be combined with other *in vitro* and *in silico* methods as part of weight-of-evidence or defined approach frameworks commonly applied in regulatory toxicology.

### Broad applicability across diverse substances

Industry collaborations and case studies confirm robust performance for:

- Occupational health-related industry chemicals
- Proteins
- Microorganisms

## Features and Benefits

### Test system

- Human dendritic-like cell line: SenzaCell<sup>®</sup>.

### Solvent

- DMSO and H<sub>2</sub>O within standard protocols.

### What it measures

- Gene expression profile of 28 genomic biomarkers.

### Readout

- Binary prediction: Respiratory sensitizer or non-sensitizer.

### Short turnaround time

- 4-8 weeks for standard studies.
- Fast track available.

### Low sample requirement

- 0.5g (solid) or 1ml (liquid).

### Compliance

- GLP-compliant laboratory.

## Scientific expertise and personal support

### *Top reasons customers test with us*

#### 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](http://www.senzagen.com/science/posters).

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

Specificity	95%
Accuracy	74%
Sensitivity	53%
Between Laboratory Reproducibility	79%

#### 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](http://www.senzagen.com/science).

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