**GARD®—next generation safety testing**

**The technology**

**GARD® platform**
GARD (Genomic Allergen Rapid Detection) is an *in vitro* platform for assessment of various toxicological endpoints using genomic-based technology. The GARD platform offers a portfolio of tests sharing the same scientific principle but focusing on different toxicological endpoints.

GARDskin is the first ready-for-market application from the portfolio and is a robust *in vitro* skin sensitization assay with the highest accuracy on the market.[1]

GARDpotency is an add-on assay to GARDskin and is a first-in-class *in vitro* test to perform CLP/GHS, 1A, 1B potency classification.[6]

**Broad applicability domain**

The **GARD® test** has a broad applicability domain and is capable of classifying substances that have proven difficult in other *in vitro* systems, such as pre- and pro- haptens. The broad range of solvents/vehicles used for GARD allows for custom designed extraction steps that also enables the assessment of complex mixtures including oils and extracts from natural products.

For application notes, please visit: www.senzagen.com/science/application-notes

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**The GARD® process in six steps**

1. **GARD® input finder**: grow SenzaCells to determine the concentration of the test substances where the cells react and 90% survive
2. **GARD® main stimulation**: expose a fresh batch of cells to the determined concentration to test the substance
3. **RNA extraction**: extract RNA from the cells using a traditional RNA extraction kit
4. **Gene expression profiling**: hybridise the RNA and quantify the RNA using the NanoString nCounter system. Output= gene expression readout
5. **GARD® data analysis application**: analyse the gene expression readouts using a SenzaGen application
6. **Results**: reporting of results in compliance with required standards

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**Results OECD validation ring trial**

<table>
<thead>
<tr>
<th>Test</th>
<th>WLR (robustness)</th>
<th>BLR (transferability)</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>DPRA (TG 442C)</td>
<td>82% (range 82-89%)</td>
<td>92%</td>
<td>94% (average over all three laboratories)</td>
</tr>
<tr>
<td>ARE-NRF2 (TG 442D)</td>
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<tr>
<td>h-CLAT (TG 442E)</td>
<td></td>
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<td></td>
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<tr>
<td>2 out of 3 ITS</td>
<td></td>
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<td></td>
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<tr>
<td>GARD (TG 4.106)</td>
<td></td>
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</table>

Results based on 69 overlapping compounds compiled in a retrospective meta-analysis covering chemicals published in four publications[2-5]. For further details, see Roberts D.W., 2018.[7]

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Robust, Safe and Secure

The GARD assay is shown to be highly robust, as demonstrated in the within (WLR) and between (BLR)-laboratory reproducibility in the ring trial for ECVAM/OECD validation.[7]

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*SenzaGen*
OECD validation status
GARDskin has been accepted for formal validation by the OECD (TGP 4.106) and shown outstanding results\(^6\). The formal OECD validation report was submitted in January 2018.

### Results OECD validation ring trial
- **Accuracy**: 96%
- **Sensitivity**: 93%
- **Specificity**: 96%

GARD\(^{\text{potency}}\)
- **Accuracy**: 82%

So far, no other test, in vitro or in vivo has shown such high accuracy\(^7,8\).

REACH and ECHA compliance
The GARDskin assay is accepted by ECHA for REACH testing and dossier filing under Annex XI and with the following official statement: "The REACH Regulation allows the use of non-adopted in vitro methods in case they meet the EURL ECVAM criteria for entering pre-validation. For the GARD assay this criteria is met" ECHA, official answer.

About us
SenzaGen is a spin-out company from Lund University located in the south of Sweden with expertise in immunology, information technology and genomics. The company is dedicated to developing innovative in vitro methods for safety testing of chemicals and ingredients. SenzaGen performs the in vitro GARD test in its own laboratory and through licenced partners around the world.

### References
1. Roberts, D.W. Is a combination of assays really needed for non-animal prediction of skin sensitization potential? Performance of the GARD (Genomic Allergen Rapid Detection) assay in comparison with OECD guideline assays alone and in combination. Regulatory Toxicology and Pharmacology, 2018
3. Asturiol et al., Consensus of classification trees for skin sensitisation hazard prediction. Toxicology In Vitro, 2016
4. Forreryd et al., From genome-wide arrays to tailor-made biomarker readout – Progress towards routine analysis of skin sensitizing chemicals with GARD. Toxicology In Vitro, 2016
6. Zeller et al., The GARD platform for potency assessment of skin sensitizing chemicals. ALTEX, 2017
7. Johansson et al., The validation of GARDskin. Abstract 3066, SOT Conference 2018
8. So far, no other test, in vitro or in vivo has shown such high accuracy.