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].

	DPRA (TG 442C)	ARE-NRF2 (TG 442D)	h-CLAT (TG 442E)	2 out of 3 ITS	GARD (TGP 4.106)
Accuracy	80%	83%	77%	83%	88%
Sensitivity	78%	84%	80%	84%	90%
Specificity	83%	78%	67%	78%	83%

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 .[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 assesment of complex mixtures including oils and extracts from natural products. For application notes, please visit: www.senzagen.com/science/application-notes

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

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]

Results OECD validation ring trial

WLR (robustness)	82% (range 82-89%)
BLR (transferability)	92%
Accuracy	94% (average over all three laboratories)

• REACH TESTING • CLP/GHS CLASSIFICATION • ANIMAL FREE • IN VITRO •

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 –average over three laboratories

Accuracy	94%
Sensitivity	93%
Specificity	96%

GARDpotency

Accuracy	82%

So far, no other test, in vitro or in vivo has shown such high accuracy [1,7].

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
2. Johansson H., et al. Evaluation of the GARD assay in a blind Cosmetics Europe study. ALTEX 2017
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
5. Johansson et al., GARD in-house validation – A proof of concept. Tox Sci, 2014
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

Test services

GARD®skin. For *in vitro* classification of skin sensitizers with an outstanding accuracy using a biomarker signature consisting of ~200 genes.

GARD®potency. For *in vitro* CLP/GHS classification (1A or 1B) of skin sensitizers using a novel biomarker signature consisting of ~50 complementing genes as an add-on assay to GARDskin and is a first-in-class *in vitro* test to perform CLP potency classification[4].

GARD®air. An *in vitro* assay for prediction of chemical respiratory sensitizers. GARDair is a first-in-class method for accurate prediction and classification of chemical respiratory sensitizers. This project has received funding from the European Union´s Horizon 2020 research and innovation programme under grant agreement No.756014.

Horizon 2020

The GARD portfolio is currently available at several contract laboratories in Europe and USA.

Pipeline projects

GARD® for materials. An *in vitro* assay for assessment of skin sensitizers of materials and Medical Device classified products.

GARD® for proteins. An *in vitro* assay for classification of protein sensitizers using the GARD platform with the support from several partner research institutes.

GARD® for mixtures. An *in vitro* assay for assessment of complex formulations and UVCBs.

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