

Conclusive data on predictive performance of GARD™ in highly regarded scientific journal

SenzaGen announces today that research on the conformal prediction of the GARD™ assay has been published in the distinguished peer reviewed journal *Toxicology in Vitro*. The research presented in the publication proves that, as the first *in vitro* model for prediction of the skin sensitizing potential of chemicals, GARD™ is now capable of providing a statistically valid measure of uncertainty for each individual prediction, thus allowing for classification of skin sensitizers with confidence. Consequently, GARD™ can meet the growing needs of high safety skin sensitization testing and particularly since there is now proof that all chemical reactivity domains, as well as pre- and pro-haptens are within GARD's applicability domain.

In the publication, *Predicting skin sensitizers with confidence — Using conformal prediction to determine applicability domain of GARD™*, a research group from Lund University, Swetox and SenzaGen reports its successful work on implementing a mathematical framework based on conformal prediction into GARD™ for the purpose of defining the applicability domain of the assay, something often neglected by test developers. Investigation of historical data within the framework demonstrates that all hitherto tested chemical reactivity domains, as well as pre- and pro-haptens are within the applicability domain of GARD, and can be predicted with a high degree of confidence. The results of this research demonstrate that the multivariate genomic biomarker signature, the unique technology of GARD makes it applicable across various chemical reactivity domains.

The mathematical framework in this implementation defines the applicability domain in terms of similarity to the samples used for model development and is capable of providing a statistically valid measure of uncertainty associated with each prediction. Furthermore, it also delivers a warning if a specific test sample is outside the region where the model is capable of generating a reliable prediction. Similar to the field of QSAR modelling, this information should be a minimal requirement for a successful validation also of *in vitro* models.

As the first *in vitro* model for prediction of skin sensitizing potential of chemicals, GARD™ is now capable of providing a statistically valid measure of uncertainty for each individual prediction, thus allowing for classification of skin sensitizers with even higher confidence. These scientific findings will benefit the chemical industry by providing better guidance of what test to use for different substances in different chemical domains and demonstrates the even broader applicability of GARD.

Full article: *Predicting skin sensitizers with confidence — Using conformal prediction to*

SENZAGEN AB

MEDICON VILLAGE,
SCHEELEVÄGEN 2
223 81 LUND, SWEDEN

P: +46 46 2756200
W: WWW.SENZAGEN.COM
E: INFO@SENZAGEN.COM

determine applicability domain of GARD **Forreryd A., Norinder U., Lindberg T., Lindstedt M.**

<https://www.sciencedirect.com/science/article/pii/S0887233318300237?via%3Dihub>

For more information:

Anki Malmborg Hager, CEO, SenzaGen AB
Email: anki.malmborg.hager@senzagen.com
Telephone: +46 768 284822

About GARD™

GARD™ is a group of tests for assessing chemical skin sensitizers. The tests make use of genetic biomarkers for more than 200 genes which cover the entire immune reaction and are relevant to predicting the risk of hypersensitivity. The tests have over 90% reliability.

This compares with the current predominant test method, experiments on mice, which has an accuracy of 70-75%. SenzaGen's tests are also capable of measuring the potency of a substance's allergenic properties. Consequently, GARD™ tests provide a much more comprehensive basis for determining whether a substance should be classified as an allergen than current testing methods.

About SenzaGen

SenzaGen makes it possible to replace animal experiments with in vitro genetic testing to determine the allergenicity of the chemicals we come into contact with in our daily lives, such as for example in cosmetics, pharmaceuticals, food products and dyes. The company's patented tests are the most reliable on the market and provide more information than traditional evaluation methods. We ourselves sell the tests in Sweden and the USA, and we sell through partners in several other countries. Over the next few years the company will expand geographically, make alliances with more distribution partners and launch further unique tests. SenzaGen has its headquarters in Lund in Sweden and a subsidiary in San Francisco, USA. For more information visit www.senzagen.com