May 10, 2016

GARD approved for validation within the OECD

GARD, Senzagen´s in vitro assay for sensitization, has been included in the OECD Test Guideline Programme (TGP) work plan with the TGP No 4.106. The decision was made at the WNT National Coordinators Test guideline programme meeting in the end of April. The validation process for GARD will now be initiated.

SenzaGen's test Genomic Allergen Rapid Detection (GARD) has been reviewed by all OECD WNT (The *Working Group* of the National Coordinators of the Test Guidelines Programme (*WNT*)) task force members and has been included in the Test Guideline Programme. This means that the process of formally validating GARD can begin. The purpose of the validation process is to show that GARD is a reproducible assay that can be use by external laboratories. The assay will be transferred externally to perform a so called "ring trial".

- This is a very important decision for the development of GARD as an international sensitization test and we are very confident we will have a successful ring trial. Even if our customers have been convinced by the quality of our test, it will make a big difference from a regulatory point of view when the test is validated, says Anki Malmborg Hager

The GARD test has been scientifically validated and has gone through successful in house validations prior to this with industrial partners. The test assay is based on a new innovative genomic technique which is argued to be the future of sensitization testing now that animal bans are more and more prevailing. As the chemical industry needs to find accurate and reliable tests, GARD will be an important player on the testing market once it has finalised its validation.

- The OECD WNT representatives were very interested and positive to the GARD test and to include it in the TGP work plan. The representatives also look forward to receiving information regarding the formal validation, when these results are available. The demand is high for new alternative test methods and it has been an interesting journey as a representative for Swedish Chemicals Agency (Kemikalieinspektionen) to present GARD to OECD as it has such great potential. I am very much looking forward to follow the future for this test, says Henrik Appelgren, national coordinator at Kemikalieinspektionen.

Two external laboratories will now test GARD on several different chemicals to confirm that the test is reproducible. This process has started and final validation is expected within one year.

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About GARD

By analyzing 200 and 389 markers, depending on the test, GARD generates massive amounts of data and delivers results with 90 % prediction accuracy. This can be compared to the golden standard, animal tests on

mice, that provides 72 % prediction. SenzaGen's test also has the ability to measure potency (strength) of a substance and can thus determine the degree to which a substance is an allergen.

About SenzaGen

SenzaGen provides dermal and respiratory in vitro testing for the cosmetic, chemical and pharmaceutical industries replacing the need for animal testing. The company's unique test GARD is based on research from the Department of Immune Technology at Lund University. SenzaGen is based at Medicon Village in Lund, Sweden.

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