TEST CODE:
CT-066

GARD®skin

Animal-Product-Free Adaptation

IN VITRO SKIN SENSITISATION TEST

OVERVIEW

Skin sensitisation is defined as an allergic response following skin contact with the tested chemical, as defined by the United Nations Globally Harmonized System for Classification and Labelling of Chemicals (UN GHS).

GARD®skin (Genomic Allergen Rapid Detection) is a non-regulatory test supporting discrimination of skin Sensitisers and Non-Sensitisers in accordance with the UN GHS. GARD®skin also provides a useful screen for product development. GARD®skin Animal-Product-Free is an adaptation of the GARD®skin method, and the data generated should be considered in the context of an integrated approach to testing. Foetal bovine calf serum (FBS) and animal derived antibodies have been replaced with human-derived serum and antibodies produced by phage display.

The adverse outcome pathway (AOP) leading to skin sensitisation involves several key events. This test addresses Key Event 3 (activation of dendritic cells), but provides also information on genes related to processes across the entire AOP.

The GARD®skin method is an *in vitro* test based on a human dendritic-like cell line (SenzaCell™), a set of 200 genes known as the GARD Prediction Signature and a prediction model developed with machine learning technology.

After exposure to the test item, total RNA is isolated from SenzaCells™, gene expression is then quantified and analysed by pattern recognition technology using a machine learning algorithm based on a fixed set of reference samples. The genes measured are well characterised and are related to several skin sensitisation mechanistic events. The resulting classification is that of a sensitiser or non-sensitiser.

TEST SYSTEM: SENZACELLS™

The test system comprises of SenzaCells™ a proprietary human dendritic-like cell line stimulated by a test item. The SenzaCell™ RNA is isolated, the gene expression is measured and the resulting data is analyzed using a machine learning algorithm.

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XCellR8 Redefining testing

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SUMMARY OF THE TEST METHOD

- An initial dose-response experiment (GARD Input Finder) is performed to determine a concentration of test item where 90% of SenzaCells™ are viable.
- In the main experiment, SenzaCells™ are dosed with the concentration determined by the GARD Input Finder for 24-hours.
- After 24-hour stimulation, the total RNA of the SenzaCells™ is extracted and isolated.
- Using the isolated RNA, the change in expression of 200 genes are measured using a NanoString.
- The results of gene expression profiling are analysed through a prediction model that correlates gene expression to sensitising potential.
- The results classify the test substance as a sensitiser or non-sensitiser.

TURNAROUND TIME	*6 – 8 weeks*
AMOUNT OF SAMPLE REQUIRED	*10ml (liquids) / 10g (solids). Please enquire if sample availability is limited.*
PRICE	*Our test prices are dependent on the quantity of test items. Please enquire for a quote using the contact information shown below, or the contact form on our website.*
FURTHER DOWNLOADS	XCellR8 Good Laboratory Practice (GLP) Compliance Certificate. Validation of the GARD®skin assay for assessment of chemical skin sensitizers – ring trial results of predictive performance and reproducibility

QUALITY STATEMENT

XCellR8 is accredited by the UK Medicines and Healthcare Products Regulatory Authority (MHRA) for the conduct of *in vitro* safety testing in compliance with Good Laboratory Practice (GLP). This means that we are able to provide you with test results that may be used at a regulatory level to demonstrate product safety, where the test is an approved regulatory method. The test method described here is non-regulatory but is conducted in our GLP-accredited laboratory.

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