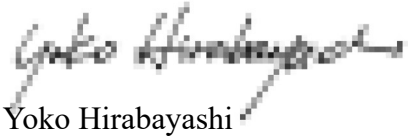
JaCVAM statement on the ARE-Nrf2 luciferase LuSens test method for skin sensitization (LuSens test method)

At a meeting held on 14 November 2019 at the National Institute of Health Sciences (NIHS) in Kanagawa, Japan, the Japanese Center for the Validation of Alternative Methods (JaCVAM) Regulatory Acceptance Board unanimously endorsed the following statement:

Proposal: A review of the LuSens test method by the JaCVAM Skin Sensitization Editorial Committee has determined that the LuSens test method exhibits a predictive capacity roughly equivalent to that of the KeratinoSens™ test method and that test chemicals yielding positive results in LuSens testing should in a regulatory context be considered strong sensitizers belonging to Category 1 of the United Nations Globally Harmonized System of Classification and Labelling of Chemicals (UN GHS). At the same time, however, it should be remembered that, as with the KeratinoSens™ test method, LuSens testing does in rare cases yield false positive results. Conversely, LuSens testing also yields false negatives, which means that it would be unreasonable to use it as a standalone test for predicting skin sensitization potential. We therefore conclude that the use of the LuSens test method in a regulatory context requires a thorough understanding of the assay's strengths and weaknesses as a prerequisite to its application within an integrated approach to testing and assessment (IATA) that will also take into account information from other sources.

This statement was prepared to acknowledge that the results of a review and study by the JaCVAM Regulatory Acceptance Board have confirmed the usefulness of this assay.
Based on the above, we propose the LuSens test method as a useful means for estimating skin sensitization by regulatory agencies.

Yasuo Ohno
Chairperson
JaCVAM Regulatory Acceptance Board



Yoko Hirabayashi
Chairperson
JaCVAM Steering Committee

November 18, 2019

The JaCVAM Regulatory Acceptance Board was established by the JaCVAM Steering Committee and is composed of nominees from industry and academia.

This statement was endorsed by the following members of the JaCVAM Regulatory Acceptance Board:

Mr. Yasuo Ohno (Kihara Memorial Yokohama Foundation for the Advancement of Life Sciences): Chairperson
Ms. Yoko Hirabayashi (Center for Biological Safety and Research: CBSR, National Institute of Health Sciences: NIHS)
Mr. Morihiko Hirota (Japan Cosmetic Industry Association)**
Mr. Yoshiaki Ikarashi (NIHS)
Mr. Noriyasu Imai (Japanese Society for Alternatives to Animal Experiments)
Mr. Kunifumi Inawaka (Japan Chemical Industry Association)
Mr. Tomoaki Inoue (Japanese Society of Immunotoxicology)
Mr. Yuji Ishii (CBSR, NIHS)
Ms. Yumiko Iwase (Japan Pharmaceutical Manufacturers Association)
Mr. Fumihiro Kubo (Pharmaceuticals and Medical Devices Agency)
Mr. Kenichi Masumura (Japanese Environmental Mutagen Society)
Ms. Ruriko Nakamura (National Institute of Technology and Evaluation)
Mr. Akiyoshi Nishikawa (CBSR, NIHS/ Saiseikai Utsunomiya Hospital)
Mr. Jihei Nishimura (Pharmaceuticals and Medical Devices Agency)
Mr. Satoshi Numazawa (Japanese Society of Toxicology)
Ms. Mariko Sugiyama (Japan Cosmetic Industry Association)*
Mr. Hiroo Yokozeki (Japanese Society for Cutaneous Immunology and Allergy)

Term: From 1st April 2018 to 31st March 2020
*: From 1st April 2018 to 31st March 2019
**: From 1st April 2019 to 31st March 2020

This statement was endorsed by the following members of the JaCVAM steering Committee after receiving the report from the JaCVAM Regulatory Acceptance Board:

Ms. Yoko Hirabayashi (CBSR, NIHS): Chairperson
Mr. Manabu Fuchioka (Ministry of Health, Labour and Welfare)
Mr. Osamu Fueki (Pharmaceuticals and Medical Devices Agency)
Mr. Akihiko Hirose (Division of Risk Assessment, CBSR, NIHS)
Mr. Masamitsu Honma (Division of Genetics and Mutagenesis, CBSR, NIHS)
Ms. Mie Ikeda (Pharmaceuticals and Medical Devices Agency)
Mr. Koji Ishii (National Institute of Infectious Diseases)
Mr. Yasunari Kanda (Division of Pharmacology, CBSR, NIHS)
Mr. Satoshi Kitajima (Division of Toxicology, CBSR, NIHS)
Mr. Yoshinobu Nosaka (Ministry of Health, Labour and Welfare)
Ms. Kumiko Ogawa (Division of Pathology, CBSR, NIHS)
Mr. Haruhiro Okuda (NIHS)
Mr. Atsuya Takagi (Animal Management Section of the Division of Toxicology, CBSR, NIHS)
Mr. Masahiro Takahata (Ministry of Health, Labour and Welfare)
Mr. Masaaki Tsukano (Ministry of Health, Labour and Welfare)
Mr. Takao Ashikaga (Division of Risk Assessment, CBSR, NIHS): Secretary
Mr. Hajime Kojima (Division of Risk Assessment, CBSR, NIHS): Secretary