

**JaCVAM statement  
on *in vitro* assays using the reconstructed human epidermis models, LabCyte EPI-  
MODEL24  
for skin irritation testing**

At the meeting concerning the above method, held on 19 April 2013 at the National Institute of Health Sciences (NIHS), Tokyo, Japan, the members of the Japanese Center for the Validation of Alternative Methods (JaCVAM) Regulatory Acceptance Board unanimously endorsed the following statement:

**The *in vitro* assay using the reconstructed human epidermis models such as LabCyte EPI-MODEL24 is considered to have sufficient accuracy and reliability for prediction of skin irritating test substances applied for 4 hours under proper conditions.**

Following the review of the results of the ECVAM (European Center for the Validation of Alternative Methods) statements and OECD (Organisation for Economic Co-operation and Development) Test Guideline revised No. 439, it is concluded that two *in vitro* assays using the reconstructed human epidermis models such as EpiDerm and SkinEthics for skin irritation testing are clearly beneficial.

The JaCVAM Regulatory Acceptance Board has been regularly kept informed of the progress of the study, and this endorsement is based on an assessment of various documents, including, in particular, the evaluation report prepared by the JaCVAM ad hoc peer review panel for skin irritation testing.



Takemi Yoshida  
Chairperson  
JaCVAM Regulatory Acceptance Board



Akiyoshi Nishikawa  
Chairperson  
JaCVAM Steering Committee

20 November, 2013

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

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

Mr. Takemi Yoshida (Japanese Society of Toxicology): Chairperson  
Mr. Norihide Asano (Japanese Environmental Mutagen Society)  
Mr. Tsutomu Ichiki (Japan Chemical Industry Association)\*  
Mr. Yoshiaki Ikarashi (National Institute of Health Sciences: NIHS)  
Mr. Tsutomu Miki Kurosawa (Japanese Society for Animal Experimentation)  
Mr. Eiji Maki (Japanese Society of Immunotoxicology)  
Mr. Mitsuteru Masuda (nominee by Chairperson)  
Mr. Akiyoshi Nishikawa (NIHS)  
Mr. Yasuo Ohno (nominee by Chairperson)\*  
Mr. Hiroshi Onodera (Pharmaceuticals and Medical Devices Agency)  
Ms. Mariko Sugiyama (Japan Cosmetic Industry Association)  
Ms. Tomoko Tanita (Pharmaceuticals and Medical Devices Agency)\*  
Mr. Takashi Yamada (National Institute of Technology and Evaluation)\*  
Mr. Hiroo Yokozeki (Japanese Society for Dermatoallergology and Contact Dermatitis)  
Ms. Midori Yoshida (NIHS)  
Mr. Isao Yoshimura (nominee by Chairperson)  
Mr. Kazuto Watanabe (Japan Pharmaceutical Manufacturers Association)

Term: From 1st April 2012 to 31st March 2014

\*: From 1st April 2013 to 31st March 2014

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

Mr. Akiyoshi Nishikawa (BSRC, NIHS): Chairperson  
Mr. Akihiko Hirose (Division of Risk Assessment, BSRC, NIHS)  
Mr. Masamitsu Honma (Division of Genetics and Mutagenesis, BSRC, NIHS)  
Mr. Jun Kanno (Division of Cellular and Molecular Toxicology, BSRC, NIHS)  
Mr. Toru Kawanishi (NIHS)  
Mr. Kenji Kuramochi (Ministry of Health, Labour and Welfare)\*  
Mr. Toshinari Mitsuoka (Ministry of Health, Labour and Welfare)  
Ms. Kumiko Ogawa (Division of Pathology, BSRC, NIHS)  
Mr. Kazuyuki Saito (Pharmaceutical & Medical Devices Agency)  
Mr. Masahiro Sasaki (Ministry of Health, Labour and Welfare)  
Ms. Yuko Sekino (Division of Pharmacology, BSRC, NIHS)  
Mr. Atsuya Takagi (Animal Management Section of the Division of Cellular and Molecular Toxicology, BSRC, NIHS)  
Mr. Junji Yamamoto (Ministry of Health, Labour and Welfare)\*  
Mr. Hajime Kojima (Section for the Evaluation of Novel Methods, Division of Pharmacology, BSRC, NIHS): Secretary

\* Arrival at post day: 1st August 2013