

**JaCVAM statement
on the LLNA-DA for skin sensitization testing**

At the meeting concerning the above method, held on 28 August 2008 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 [1] unanimously endorsed the following statement:

Following the review of the results of the Ministry of Health, Labour and Welfare (MHLW)-funded validation study on the LLNA (Local Lymph Node Assay) -DA coordinated by Japanese Society for Alternative to Animal Experiments (JSAAE), it is concluded that the LLNA-DA can be used for distinguishing between sensitizer and non-sensitizer chemicals within the context of the OECD testing guideline No. 429 on Skin sensitization: LLNA.

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 report on the results from the study, and also on the evaluation supported by JSAAE of the study prepared for the JaCVAM ad hoc peer review panel.



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Tetsu Inoue,
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4 November 2008

1. 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. Tohru Inoue (NIHS)
Mr. Makoto Hayashi (An-pyo Center*)
Mr. Noriho Tanaka (FDSC*)
Mr. Takemi Yoshida (Showa Univ.)
Ms Masako Mizoguchi (St. Marianna Univ. School of Medicine)
Mr. Fumio Sagami (Eisai Co., Ltd./JPMA*)
Ms Yuko Okamoto (KOSÉ Corporation/JCIA*)
Mr. Hiroshi Onodera (PMDA*)
Mr. Yoshiaki Ikarashi (NIHS)

The following members of the JaCVAM Steering Committee were involved as observers in the consultation process, but not in the endorsement process itself.

Mr. Yasuo Ohno (NIHS)
Mr. Kenichi Nakazawa (NIHS)
Mr. Hiroshi Itagaki (JSAAE)
Mr. Mitsuteru Masuda (JaCVAM)
Mr. Hajime Kojima (JaCVAM)

* An-pyo Center: Biosafety Research Center Food, Drugs and Pesticides
FDSC: Food and Drug Safety Center
PMDA: Pharmaceuticals and Medical Devices Agency
JPMA: Japan Pharmaceutical Manufacturers Association
JCIA: Japan Cosmetic Industry Association