

**JaCVAM statement
on the Local Lymph Node Assay (LLNA): BrdU-ELISA
for skin sensitization assay**

At the meeting concerning the above method, held on 1 October 2012 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:

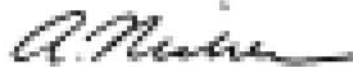
The LLNA: BrdU-ELISA can be used to identify substances as potential skin sensitizers or nonsensitizers as well as LLNA for regulatory use, without Radio-isotope.

Following the review of the results of the ICCVAM (Interagency Coordinating Committee on the Validation of Alternative Methods, USA) Evaluation Report, JaCVAM peer review panel reports, and OECD (Organisation for Economic Co-operation and Development) Test Guideline revised No. 442B, it is concluded that the LLNA: BrdU-ELISA for skin sensitization assay is 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 sensitization assay.



Takemi Yoshida
Chairperson
JaCVAM Regulatory Acceptance Board



Akiyoshi Nishikawa
Chairperson
JaCVAM Steering Committee

20 January, 2013