First evaluation report on the LLNA：DA for skin sensitization testing

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Summary

Per a determination made by the Health Sciences Group in 2003, an LLNA-DA test method for sessing skin-sensitization potency without using radioisotope-labeled compounds, as proposed by Daicel Chemical Industries, was evaluated as an alternative to the local lymph node assay (LLNA). In response, the Peer Review Panel organized a skin-sensitization potency test working group. A preliminary review of the applicant's data by the working group determined LLNA-DA to have merit in that it was based on the same principle as the original LLNA, was equally efficacious in identifying skin-sensitization, did so without using radioisotopes, was simple and convenient, and produced results in a short period of time. In order to evaluate suitability as a regulatory test method, however, additional information about eliability of data and interlaboratory variation is needed. For that purpose the Validation Committee of the Japanese Society for Alternative to Animal Experiments was requested to conduct a multi-laboratory validation.