

Updated NICEATM Evaluation and International Acceptance of the Reduced Murine Local Lymph Node Assay

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To minimize allergic contact dermatitis (ACD) occurrence, regulatory authorities require testing to identify substances with ACD potential. Such substances must be labeled with the hazard description and precautions necessary to minimize exposure. The murine local lymph node assay (LLNA) is an alternative test method for determining the ACD hazard potential of most types of substances and compared to guinea pig tests requires fewer animals, less time, and eliminates pain and distress. The reduced LLNA (rLLNA), which uses only the high dose, further reduces animal use by 40% compared to the multidose LLNA. LLNA results from 1071 published and unpublished studies, representing 664 unique substances, were obtained. Accuracy for the rLLNA was 98.4% (1054/1071), with false positive and false negative rates of 0% (0/319) and 2.3% (17/752), respectively. These results reinforce ICCVAM's 2009 recommendation (which was based on 471 LLNA studies) that the rLLNA be routinely considered before conducting the multidose LLNA, when dose-response information is not required. Based on the ICCVAM/NICEATM joint evaluation, the rLLNA was included in an updated version of the OECD Test Guideline for the LLNA (TG 429) that was adopted in 2010. The availability of this international TG will allow for global use of the rLLNA for regulatory testing, which is expected to significantly reduce animal use for ACD hazard testing while supporting the protection of human health. The views above may not represent the official position of any government agency. ILS staff supported by NIEHS contract N01-ES-35504.

Theme: I-11 Safety Testing for Skin Sensitization Hazards: Recent Three Rs Advances

Keywords: murine local lymph node assay (LLNA); reduced LLNA; three Rs; alternative methods