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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 21827-2025

Replacing GB/T 21827-2008

**Chemicals - Test method of skin sensitization - Local lymph
node assay**

化学品 皮肤变态反应试验 局部淋巴结方法

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1. Structure and Drafting Rules of Standardization Documents". Drafting. This document supersedes GB/T 21827-2008 "Local Lymph Node Method for Skin Allergic Reactions of Chemicals", and is consistent with... Compared with GB/T 21827-2008, apart from structural adjustments and editorial changes, the main technical changes are as follows: A new chapter on terms and definitions (see Chapter 3) and a new chapter on abbreviations (see Chapter 4) have been added. Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents. This document was proposed and is under the jurisdiction of the National Technical Committee on Standardization of Hazardous Chemicals Management (SAC/TC251). This document was drafted by: the Institute of Occupational Health and Poison Control, Chinese Center for Disease Control and Prevention, and the Huludao Municipal Center for Disease Control and Prevention. Zhongke Standard (Ningde) Technology Co., Ltd. The main drafters of this document are: Zheng Min, Yang Guoqing, Li Bin, Cheng Juan, Wu Zhijun, Zhang Yi, Yu Tao, Chen Xiao, Xiao Jingwei, Liu Li, and Lin Ying. The release history of this document and the document it replaces is as follows:

---First published in 2008 as GB/T 21827-2008;

---This is the first revision.

The local lymph node method in allergy testing is one of the commonly used methods for detecting skin allergic reactions induced by exogenous chemicals. This method assesses the skin effects of chemical substances by measuring the proliferative activity of lymphocytes in local skin lymph nodes during the induction phase of sensitization. Skin allergic reaction effects and intensity. In 2008, the Standardization Administration of China organized the release of GB/T 21827-2008 "Topical Tests for Skin Allergic Reactions of Chemicals". The Lymph Node Method (LLNA test) specifies the scope, basic principles, methods, data, and reporting of the LLNA test. The content and technical requirements are currently the only test method besides guinea pig sensitization tests that can be used to assess the skin sensitization of test substances. LLNA This is an in vivo experiment, and

the results are presented as quantifiable lymphocyte proliferation data, with the degree of proliferation being directly proportional to the dose of the test substance. The toxicological dose-response relationship method for assessing the sensitization potential of a test substance is more objective and reliable than traditional sensitization tests. Compared to other methods, LLNA assays have a shorter cycle, do not require secondary exposure to the allergen, avoid harm to experimental animals during the challenge phase, and take into account animal welfare. The benefits are in line with the 3R principle of animal testing. GB/T 21827-2008 has been in effect for over ten years, and its application and implementation have been... In China, as the ethical requirements for laboratory animals receive increasing attention, theoretical research, practice, and international norms related to this method are also constantly evolving. The situation is constantly changing; meanwhile, the mandatory national standard GB 14925-2023 was released in 2023, which sets higher requirements for the environment and facilities for laboratory animals. To ensure precise and scientific regulations and requirements, it is necessary to revise GB/T 21827-2008 to continuously adapt to new changes in relevant domestic and international standards. To meet new demands, we must ensure that LLNA testing is continuously updated and improved at the technical and methodological level. Both the LLNA test and the guinea pig sensitization test can be used to identify most potential sensitizing chemicals. Before starting the LLNA test, the experiment... The laboratory needs to have a thorough understanding of the chemical structure, physicochemical characteristics, and toxicological information of the test substance to confirm whether LLNA can be used. The test method is used to assess skin sensitization to the test substance. The LLNA test is not a substitute for the guinea pig skin sensitization test, although... This testing method has advantages, but it also has certain limitations, such as certain metals, skin irritants, high molecular weight substances, and substances containing pesticide components. Exogenous chemical substances, etc., may interfere with the accuracy of LLNA testing methods due to their physicochemical properties, and may result in false positive results or inapplicability. Furthermore, at this point, it is necessary to consider using reference materials to validate the LLNA test system and to conduct further testing using traditional guinea pig sensitization tests. Verify in one step. Chemical skin allergy test Local lymph node method

1 Scope

GB/T 21827-2025 is the Chinese national standard on chemicals - test method of skin sensitization - local lymph node assay, in the field of environment and health protection, safety. The /T suffix marks it as a recommended standard: it is not compulsory by itself, but it becomes binding as soon as a contract, a tender or a customer specification calls it up - which in practice is how most foreign buyers meet it. It was issued on 5 October 2025 by the State Administration for Market Regulation; Standardization Administration of China, and has been in force since 1 February 2026. Classification: ICS 13.300, CCS A80. This page is published from the official record of the standard held by the Chinese standards

administration: the identification, the dates, the classification and the issuing body are taken from there. The clause text, the tables and the numeric limits are in the document itself, which is delivered complete in English translation.

This document establishes the basic principles of the local lymph node method for skin allergy testing and specifies the content of test data and reports. The requirements describe the experimental methods and procedures. This document applies to the detection of chemical-induced skin allergic reactions and provides quantitative data for assessing dose-response relationships.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included. For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies. This document.

GB 14925 Laboratory Animal Environment and Facilities

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 Skin sensitization A skin allergic reaction induced by local skin exposure to chemical allergens in susceptible individuals.

3.2 test substance Chemicals for which sensitization assessment is conducted.

3.3 Stimulation Index (SI) The ratio of lymphocyte proliferation rate in the dosage group to that in the negative control group.

3.4 Reference chemicals Substances used to evaluate and verify the accuracy and reliability of test methods.

Note. Reference chemicals have the following characteristics. (1) their action characteristics and mechanisms of action have been confirmed; (2) their chemical types are clearly defined and representative; (3) they are tested. The scope covers all sensitization reaction types from strong positive, weak positive to negative; (4) different reference chemistry is selected according to the test type and verification method. substance.

3.5 Used as a standard sensitizing or non-sensitizing substance for comparison with the test subject.

Note. Reference materials have the following characteristics. (1) consistent and reliable material source; (2) structural and functional similarity to the type of substance being tested; (3) clearly defined material. (4) There is supporting data related to toxic effects; (5)

The dose or concentration within the range of the estimated toxic effects is known.

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