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

GB/T 42580-2023

**Intelligent laboratory - Microbial identification platform with
mass spectrometry**

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Foreword

This document is in accordance with the provisions of GB/T 1:1-2020 "Guidelines for Standardization Work Part 1: Structure and Drafting Rules for Standardization Documents" drafting: Please note that some contents of this document may refer to patents: The issuing agency of this document assumes no responsibility for identifying patents: This document is proposed by China Machinery Industry Federation: This document is under the jurisdiction of the National Laboratory Instruments and Equipment Standardization Technical Committee (SAC/TC526): This document is drafted by: Beijing Xinhui Purui Technology Development Co., Ltd., Machinery Industry Instrumentation Comprehensive Technology and Economic Research Institute, Qinhuang Island Customs Technology Center, Guangzhou Laiboshikai Technology Co., Ltd., Beijing Xinhui Maike Biotechnology Co., Ltd., Beijing Yixin Bochuang Biotechnology Co., Ltd: Technology Co., Ltd., Beijing Institute of Technology, Guangzhou Hexin Instrument Co., Ltd., Zhejiang Tailin Life Science Co., Ltd., Zhijiang Laboratory, Beijing Automec Technology Co., Ltd., Beijing University of Technology, Beijing Dongxi Analytical Instrument Co., Ltd., Xiamen Jinnuohua Biotechnology Co., Ltd: Co., Ltd., Rongzhi Biotechnology (Qingdao) Co., Ltd., Shandong Yingsheng Biotechnology Co., Ltd: The main drafters of this document: Zhu Jiaqiang, Liu Liqin, Zhang Guiling, Lu Tielin, Cao Rui, Qian Yunkai, Tang Jun, He Ying, Ma Qingwei, Shen Zhilin, Xu Wei, Kong Lingqin, Cheng Yang, Li Lei, Li Zhenting, Li Yong, Wu Yuxiao, Gao Liyan, Liu Hongtao, Li Yuntao, Guo Qilei: Intelligent laboratory microbial mass spectrometry identification platform

1 Scope

GB/T 42580-2023 covers the mass spectrometry platform that has largely replaced biochemical testing for identifying microorganisms. MALDI-TOF reads the protein fingerprint of a colony and matches it against a reference library, turning an identification that used to take a day or more into one that takes minutes - which is why it now sits in clinical microbiology, food safety and environmental laboratories. Its answers are only as good as

things that are easy to neglect: the library it matches against, the calibration of the instrument, the sample preparation, and the traceability of the result back to the sample it came from. This document specifies the general requirements for such platforms in an intelligent laboratory, together with the operational assurance and the management requirements that keep them dependable in daily use. It applies to the design, construction, operation and maintenance of microbial mass spectrometry identification platforms in intelligent laboratories. Under ICS 35.240.50 and CCS N61, it is written for the laboratories deploying these systems, for the vendors integrating instrument and information system, and for the accreditation bodies that have to judge whether an identification produced this way is defensible.

This document specifies the general requirements, operation guarantee and management requirements for microbial mass spectrometry identification platforms in intelligent laboratories: This document is applicable to the design, construction, operation and maintenance of microbial mass spectrometry identification platforms in intelligent laboratories:

2 Normative references

The contents of the following documents constitute the essential provisions of this document through normative references in the text: Among them, dated references For documents, only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to this document:

GB 4789:28-2013 National Food Safety Standard Quality Requirements for Food Microbiology Examination Medium and Reagents

GB/T 22239-2019 Basic Requirements for Network Security Level Protection of Information Security Technology

GB/T 32400-2015 Information Technology Cloud Computing Overview and Vocabulary

GB/T 33682-2017 General rules for the identification of microorganisms by matrix-assisted laser desorption ionization time-of-flight mass spectrometry

3 Terms and Definitions

The following terms and definitions defined in GB/T 32400-2015 and GB/T 33682-2017 apply to this document: 3:1 identification report identification report After the sample is compared with the data in the database, the obtained information includes the species name of the sample, map comparison and other information data or files: 3:

2 Quality control strain qualitycontrolstrain Strains used to calibrate time-of-flight mass spectrometers: 3:

3 Intelligent laboratory intelligentlaboratory A laboratory that uses information and communication technology to intelligently manage laboratory activities through information management systems and other systems: [Source: GB/T 40343-2021, 3:1] 3:

4 Compare and identify the data in the sample file of the peptide mass fingerprint by means of network transmission, and then transfer the identified biological The classification conclusion is sent back to the laboratory information management system (3:5) or the software platform that issues the appraisal report (3:1):

Note: The sample files of peptide mass fingerprints come from matrix-assisted laser desorption ionization time-of-flight mass spectrometry (MALDI-TOFMS) acquisition: 3:5 A computer system that manages laboratory activity data by means of acquisition, analysis, reporting, and storage:

Note: Data used in this document refers to all structured and unstructured data and information in the laboratory, not just test data: