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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 46943-2025

Clinical laboratory testing and in vitro diagnostic test systems - General requirements for the validation of metagenomic next-generation sequencing

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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. 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 by the National Medical Products Administration. This document is under the jurisdiction of the National Technical Committee on Standardization of Medical Clinical Laboratory and In Vitro Diagnostic Systems (SAC/TC136). This document was drafted by: Peking Union Medical College Hospital, Chinese Academy of Medical Sciences; National Institutes for Food and Drug Control, West China Hospital of Sichuan University; and other relevant institutions. The First Affiliated Hospital of Shandong University, The First Affiliated Hospital of China Medical University, Institute of Pathogenic Biology, Chinese Academy of Medical Sciences, Institute of Microbiology, Chinese Academy of Sciences Institute of Biology, Zhujiang Hospital of Southern Medical University, Affiliated Hospital of University of Electronic Science and Technology of China (Sichuan Provincial People's Hospital), Affiliated Hospital of Guangzhou Medical University The First Affiliated Hospital of Zhejiang University School of Medicine, the Institute for Infectious Disease Control and Prevention of the Chinese Center for Disease Control and Prevention, and Huashan Hospital Affiliated to Fudan University The hospital and the Beijing Institute for Medical Device Testing (Beijing Medical Biological Protective Equipment Testing and Research Center). The main drafters of this document are. Xu Yingchun, Huang Jie, Yang Qiwen, Chen Bojiang, Chen Peisong, Zhang Dong, Liu Donglai, Wang Jing, Wang Ruizhi, and Ren Shanshan. Han Xiaoxu, Ren Lili, Wu Linhuan, Guan Wenda, Jiang Li, Zhou Haijian, Zhang Wenhong, Zhou Hongwei, Chen Dingqiang, Zhang Jie, Xiao Yan, Yang Zifeng, Jiang Juan, Ai Lu, Dong Xiaolong, Han Dongsheng, Zhao Qianwen, Zuo Liyuan, Lu Xin, Hu Jinrui, Wang Huiru, Zou Yingshu. Clinical laboratory testing and in vitro diagnostic systems High-throughput sequencing performance of pathogen metagenomics Confirm General Requirements

1 Scope

GB/T 46943-2025 is the Chinese national standard covering validating metagenomic sequencing as a diagnostic - sequencing everything in a sample and asking what pathogen is there, which means the analytical performance has to be established against an open set of organisms rather than a defined panel, and the background of human and environmental DNA has to be handled. It is how an unknown infection gets identified when every targeted test comes back negative. First edition, in force from 1 January 2027. It was issued on 31 December 2025 and takes effect on 1 January 2027, as a first edition. The document is under the responsibility of the National Medical Products Administration. This page is published from the official record of the 2025 edition; the clause text of a standard this recent is not yet in circulation, and the figures, limits and tables it contains are those of the document itself, delivered in full with the English translation.

This document specifies the procedures for clinical testing laboratories to conduct metagenomic next-generation sequencing (MRGS). This document applies to clinical testing laboratories using high-throughput sequencing technology to perform mNGS performance validation. This document does not apply to the performance validation of single-molecule pathogen sequencing that uses biological nanopores, solid-state nanopores, or similar technologies as its primary technical principles. This method is not applicable to the performance validation of pathogen sequencing established using targeted probe hybridization capture or multiple primer amplification techniques.

2 Normative references

This document has no normative references.

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 Characterized by the ability to sequence hundreds of thousands to millions of nucleic acid molecules simultaneously and generally with short read lengths, it is suitable for DNA sequencing. technology. [Source: GB/T 30989-2014, 3.19, with modifications]

3.2 A detection technique for unbiased sequencing of the DNA and/or RNA of all pathogenic microorganisms in a specimen. [Source: ISO /T S24420.2023, 3.23, with modifications]

3.3 Performance validation The determination that a specific intended use or application requirement has been met by providing objective evidence. [Source: GB/T 19000-2016, 3.8.13, with modifications]

3.4 The length of the longest gene fragment that can be sequenced is usually expressed in

terms of the number of bases. [Source: GB/T 30989-2014, 3.24]

3.5 Library A reconstructed molecular group obtained through biological, synthetic, or cloning techniques. Examples. genomic libraries, complementary DNA libraries, phage display peptide libraries, etc.