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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 46660-2025

General technical requirements for whole genome sequencing of SARS-CoV-2

新型冠状病毒全基因组测序通用技术要求

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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: China National Institutes for Food and Drug Control, BGI Genomics Co., Ltd., and West China Hospital of Sichuan University. Beijing Hospital, Yuguo Biotechnology (Beijing) Co., Ltd., Tianjin Golden Key Medical Technology Co., Ltd., Guangzhou Micro-Gene Technology Co., Ltd., and Bo J. (Qingdao) Medical Technology Co., Ltd., Jiangsu Hongweites Pharmaceutical Technology Co., Ltd., Jiangsu ShuoShi Biotechnology Co., Ltd., Beijing Beijing Municipal Institute for Medical Device Testing (Beijing Municipal Medical Biological Protective Equipment Testing and Research Center), Shenzhen Municipal Center for Disease Control and Prevention, China Customs Scientific and Technological Research Center, Institute of Microbiology, Chinese Academy of Sciences, Institute of Pathogenic Biology, Chinese Academy of Medical Sciences, Beijing Base of Chinese Academy of Sciences Genomics Institute (National Center for Biotechnology Information). The main drafters of this document are. Liu Donglai, Zhao Lanqing, Hu Jinjun, Wang Yicong, Zhao Ying, Wang Zhoufeng, Zhang Rui, Xia Han, Li Lifeng, and Zhang Junjie. Zhang Chunlei, Liu Licheng, Zhang Rong, Li Da, Lü Ziquan, Wang Yikai, Ren Yujie, Wu Linhuan, Ren Lili, Li Mingkun. Whole genome sequencing of novel coronavirus General technical requirements

1 Scope

GB/T 46660-2025 is the Chinese national standard covering sequencing the virus properly - the sample and its viral load threshold, the library preparation and the amplicon or capture approach, the depth and coverage required for a usable consensus, the quality metrics and the lineage assignment. First edition, under the National Medical Products Administration.

In force from 1 November 2026. Issued on 31 October 2025, it takes effect on 1 November 2026.

This document specifies the requirements for whole-genome sequencing methods for the novel coronavirus and describes the corresponding experimental methods. This document applies to oropharyngeal swabs, nasopharyngeal swabs, airway aspirates, sputum, bronchoalveolar lavage fluid, other respiratory secretions, or viral cultures. Whole genome sequencing of the novel coronavirus in samples such as organisms, including metagenomic sequencing and multiplex polymerase chain reaction (PCR) sequencing. And hybridization capture sequencing, etc. The sequencing principles applicable to this document include reversible terminal termination sequencing, combined probe-anchored polymerization sequencing, and single-molecule nanopore chain sequencing. Laws, etc.

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 19489-2008 General Requirements for Laboratory Biosafety

GB/T 19495.2-2004 Technical Requirements for Laboratories Testing Genetically Modified Products

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 gene sequencing The determination of different base types in nucleic acid molecules, namely, the determination of adenine (A), guanine (G), cytosine (C), and thymine that make up nucleic acid molecules. The composition or sequence of bases such as adenine (T) or uracil (U). [Source: YY/T 1723-2020, 3.1]

3.2 Whole-genome sequencing of the novel coronavirus was performed to obtain complete genomic information.

3.3 Using the entire community in a specific environment as the research object, without isolation and culture, all RNAs were directly extracted and synthesized through reverse transcription. After DNA was added, gene sequencing was performed. [Source: GB/T 40226-2021, 3.3, with modifications]

3.4 Multiplex PCR Multiplex polymerase chain reaction (PCR) is an amplification process that uses two or more pairs of primers to simultaneously amplify multiple nucleic acid fragments in the same amplification reaction system.