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

**GB/T 46942.1-2025**

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**Single-molecule gene sequencing - Part 1: Terminology**

单分子基因测序 第1部分：术语

**Issued on: December 31, 2025**

**Implemented on: January 1, 2027**

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**Issued by: State Administration for Market Regulation;  
Standardization Administration of the PRC**

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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 is Part 1 of GB/T 46942 "Single-molecule gene sequencing". GB/T 46942 has already published the following parts.

1. Terminology. 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 Institute (Shenzhen), and Beijing Qitan Technology Co., Ltd. Beijing Berry Genomics Co., Ltd., Beijing Puyi Biotechnology Co., Ltd., Anxuyuan Biotechnology (Shenzhen) Co., Ltd., Chengdu Jinshi Technology Co., Ltd., Zhejiang Dipu Diagnostic Technology Co., Ltd., China Customs Science and Technology Research Center, Beijing Medical Device Inspection and Research Institute Research Institute (Beijing Medical Biological Protective Equipment Testing and Research Center), Hunan Provincial Institute for Drug Control, Beijing Hope Group Biotechnology Co., Ltd. The company, Nanospectrum Technology (Shanghai) Co., Ltd., and Parfic (Shanghai) Biotechnology Co., Ltd. The main drafters of this document are. Huang Jie, Zeng Tao, Dong Yuliang, Lin Jianxun, Mao Aiping, Liu Kesheng, Dong Lizeng, Su Yunpeng, Guo Huimin, and Wang Yikai. Ren Yujie, Wang Ruixia, Liu Yuanyuan, Wang Yang, Pu Zijing, Xi Rui, Li Lili, Zhang Wenxin.

Single-molecule gene sequencing is a next-generation gene sequencing technology that enables long-read, rapid, real-time, and direct detection of gene modifications, following high-throughput gene sequencing. The technology, whose core feature is the continuous observation and analysis of signals generated by individual nucleic acid molecules, thereby achieving sequence determination. This requires starting from the technology... Language, sequencer performance evaluation, sample processing specifications and quality

requirements, data quality control requirements and analysis procedures and formats, as well as software requirements, etc. In this regard, establish systematic technical specifications and requirements. GB/T 46942, "Single-molecule gene sequencing," aims to define the terminology, sequencer performance evaluation, and sample processing standards for single-molecule gene sequencing. The document outlines five key requirements. quality requirements, data quality control requirements, analysis procedures and formats, and software requirements.

1. Terminology. The purpose is to define the relevant terminology and definitions for single-molecule gene sequencing, and to clarify the characteristics of continuous sequencing. Key parameters and technical terms for single-molecule gene sequencing.

2. Sequencing Instrument Performance Evaluation. The purpose is to specify the requirements for performance evaluation of single-molecule gene sequencers and describe the corresponding test... Verification method.

3. Sample Processing Standards and Quality Requirements. The purpose is to standardize the sample types and processing methods applicable to single-molecule gene sequencing. This processing technical requirement specifies the sample quality requirements and evaluation methods.

4. Data Quality Control Requirements, Analysis Process, and Format. The purpose is to specify data quality requirements and evaluation methods, and to describe the measurement... The analysis process from sequence signal to base sequence, as well as the sequencing sequence hierarchy directory format and overall data format.

5. Software. The purpose is to define the software architecture for bioinformatics analysis of single-molecule gene sequencing data. General requirements, specific requirements and testing methods, as well as computer configuration requirements and interface specifications for sequencing software. Single-molecule gene sequencing Part

## 1 Scope

GB/T 46942.1-2025 is the Chinese national standard covering the vocabulary of single-molecule sequencing - the nanopore and real-time methods that read one DNA strand without amplifying it, the read length and accuracy terms, the basecalling and the error profile peculiar to the technique. Part 1 of the series, first edition, in force from 1 January 2027, under the National Medical Products Administration. 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 defines the terminology and definitions in the field of single-molecule gene

sequencing. This document applies to technologies such as single-molecule real-time fluorescence sequencing, single-molecule nanopore chain sequencing, and single-molecule nanopore tagging sequencing. The field of single-molecule gene sequencing, characterized by continuous sequencing, is based on key technological principles. The parameter and technical terms used in this document are not applicable to.

---The first generation of gene sequencing, based primarily on Sanger sequencing technology;

---Semiconductor sequencing, reversible terminal termination sequencing, combined probe anchoring ligation sequencing, combined probe anchoring polymerization sequencing, and pyrolysis sequencing. The field of large-scale parallel high-throughput sequencing, which uses techniques such as phosphorylation sequencing as its main technical principle;

---Single-molecule gene sequencing technology that utilizes multiple discrete steps for non-continuous sequencing;

---Single-molecule long-fragment gene sequencing technology that uses co-labeling for short sequence ligation.

## 2 Normative references

This document has no normative references.

### 3.1 General Terminology

3.1.1 gene As the basic unit of genetic information, it is a nucleotide sequence that encodes a specific functional product (such as a protein or RNA molecule). [Source: GB/T 30989-2014, 3.1, with modifications]

3.1.2 genome The sum of all genetic information possessed by an organism. [Source: GB/T 30989-2014, 3.2, with modifications]

3.1.3 nucleic acid Macromolecules that act as carriers of genetic information or mediators in information expression.

Note. There are two types of nucleic acids, deoxyribonucleic acid (3.1.4) and ribonucleic acid (3.1.5). [Source: GB/T 39367.1-2020, 3.35, with modifications]

3.1.4 Deoxyribonucleotide polymers existing in double-stranded (dsDNA) or single-stranded (ssDNA) form. [Source: GB/T 39367.1-2020, 3.18]

3.1.5 ribonucleic acid ribonucleic acid; RNA Ribonucleotide polymers that exist in double-stranded or single-stranded form.