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

**GB/T 44322-2024**

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**Forensic sciences - Basic requirements for quality of next  
generation sequencing-based reagents**

法庭科学 二代测序试剂质量基本要求

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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 is required. Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents. This document is issued by the Ministry of Public Security of the People's Republic of China. This document is under the jurisdiction of the National Technical Committee on Criminal Technology Standardization (SAC/TC 179). This document was drafted by: Ministry of Public Security Identification Center, Beijing Genomics Institute of the Chinese Academy of Sciences (National Bioinformatics Center), Sichuan University Liaoning Provincial Public Security Department, Beijing Institute of Biomedicine, China University of Political Science and Law, Dalian Public Security Bureau, Aigitaikang Biotechnology (Beijing) Co., Ltd. Company, Qiagen Enterprise Management (Shanghai) Co., Ltd., Shenzhen BGI Forensic Technology Co., Ltd., and Thermo Fisher Scientific (China) Co., Ltd. The main drafters of this document are: Wang Le, Kang Keli, Ye Jian, Ji Anquan, Xiang Fangdong, Wang Zheng, Zhao Lei, Ma Wenhua, Liu Feng, Tian Xuemei, Dai Wenshen, Zhang Chi, Yuan Li, Li Mingguang, Zhao Jie, Hang Xingyi, Niu Huiyuan, Guo Xiaosen, Zhou Yishu. Basic quality requirements for forensic science next-generation sequencing reagents

### 1 Scope

GB/T 44322-2024 sets the basic quality requirements for next generation sequencing reagents used in forensic science. Massively parallel sequencing has changed forensic DNA work by reading the sequence of an STR allele rather than only its length, and by making SNPs, microhaplotypes and mitochondrial DNA routine; but a result that will be offered in evidence is only as sound as the reagent kit that produced it, and until this document there was no Chinese quality baseline for those kits. The standard sets the

technical requirements for reagents covering human DNA genetic markers, STRs, SNPs, microhaplotypes and mitochondrial DNA among them, describes the corresponding test methods, and sets the packaging, labelling and accompanying documents. Its principal working content is Annex A, forty-nine pages giving the reference profiles of the positive control DNA samples commonly used in forensic science, the material against which any kit is checked; a second annex gives the samples used for inhibitor tolerance testing, which matters because casework DNA arrives contaminated with substances that inhibit the reaction. It applies to the production, quality testing and use of forensic next generation sequencing reagents.

This document specifies the requirements for forensic human DNA genetic markers (such as STR, SNP, microhaplotype, mitochondrial DNA, etc.) next generation sequencing. The technical requirements for the reagents, packaging labels and accompanying documents describe the test methods. This document applies to the production, quality testing and use of forensic science next-generation sequencing reagents.

## 2 Normative references

The contents of the following documents constitute the essential clauses of this document through normative references in this document. For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to This document.

GB/T 43636 Forensic Science DNA Next Generation Sequencing Test Specification

GB/T 43635 Forensic Science DNA Laboratory Testing Specification

GB/T 44393 Nomenclature of sequence polymorphism STR alleles

### 3.1 Terms and Definitions The terms and definitions defined in

GB/T 43636 and the following apply to this document.

3.1.1 Balance An evaluation indicator that measures the distribution of sequencing signals between heterozygous alleles at the same locus and between different loci.

3.1.2 Allele coverage ratio; ACR The ratio of the lower to the higher sequencing depth of the two alleles when the locus is typed as heterozygous.

3.1.3 Sensitivity The minimum amount of DNA sample required for the reagent to successfully detect all loci contained in the sample under the recommended conditions and to correctly type the DNA.

20 In sequencing data, a base call quality value of 20 has a base call accuracy of 99%, or an error rate of 1%. [Source: GB/T 40226-2021, 3.5]

30 In the sequencing data, a base call quality value of 30 has a base call accuracy of 99.9%, or an error rate of 0.1%. [Source: GB/T 40226-2021, 3.6]

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