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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 42077-2022

Biotechnology - Requirements for evaluating the performance of quantification methods for nucleic acid target sequences - qPCR and dPCR

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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.

This document is equivalent to ISO 20395.2019 "Performance Evaluation Requirements for Biotechnology Nucleic Acid Target Sequence Quantitative Methods qPCR method and dPCR method.

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 was proposed and managed by the National Biochemical Testing Standardization Technical Committee (SAC/TC387).

1 Scope

This document specifies general requirements for the performance evaluation and quality assurance of methods for the quantification of nucleic acid target sequences.

This document applies to digital PCR (dPCR) or real-time quantitative PCR (qPCR) amplification techniques for DNA (deoxyribonucleic acid) and

Quantitative determination of RNA (ribonucleic acid) target sequences. Suitable target nucleic acid molecules, including double-stranded DNA (dsDNA), such as genomic

DNA (gDNA) and plasmid DNA; single-stranded DNA (ssDNA), complementary DNA (cDNA), single-stranded RNA (ssRNA) including ribosomes

RNA (rRNA), messenger RNA (mRNA); double-stranded RNA, including long and short non-coding RNA [microRNA (miRNA) and

small interfering RNA (siRNA), etc.].

This document applies to nucleic acids of biological origin (such as viruses, prokaryotic and eukaryotic cells), cell-free biological fluid samples (such as plasma or cell

cellular matrix); in vitro extracted from nucleic acids of non-biological origin [such as oligonucleotides, synthetic gene fragments, and in vitro transcribed (IVT) RNA]

nucleic acid.

This document is not intended for the quantification of DNA oligonucleotides that are too short (< 50 bases).

This document contains.

---Assay design, including quantitative strategies (qPCR standard curve method, dPCR molecular counting method, qPCR relative quantification method, dPCR ratio

value quantification method) and usage control;

--- Quantification of total nucleic acid mass concentration and quality control of nucleic acid samples, including assessment of nucleic acid quality (purity and integrity);

---PCR assay design, optimization, bioinformatics and in vitro specificity testing;

---Data quality control and analysis, including acceptance criteria, threshold setting and normalization method;

--- Method validation according to the specific requirements of qPCR/dPCR (precision, linearity, limit of quantification, limit of detection, correctness and robustness);

--- Methods for establishing metrological traceability and evaluating uncertainty of measurement.

This document does not provide advice on the sampling of biological material or the handling of biological samples (e.g. collection, preservation, transport, storage, handling, and nucleic acid extraction).

requirements or acceptance criteria. There are also no requirements and requirements for special applications (such as food or clinical applications where special matrix problems may arise)

Acceptance Criteria.

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.

ISO /IEC Guide 98-3.2008 Uncertainty of Measurement Part 3.Guidelines for the Expression of Uncertainty in Measurement (GUM.1995)

1995)]

Note. GB/T 27418-2017 Evaluation and Expression of Measurement Uncertainty (ISO /IEC Guide 98-3.2008, MOD).

ISO /IEC Guide 99 Basic and general concepts of the international vocabulary of metrology and related terms (VIM) [International