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

GB/T 42753-2023

**General principles for performance evaluation of quantitative
real-time polymerase chain reaction analyzer**

实时荧光定量PCR仪性能评价通则

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Foreword

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1 Scope

GB/T 42753-2023 sets the general principles for evaluating the performance of real-time quantitative PCR instruments. China installed an enormous number of these machines after 2020, from many suppliers and of very uneven quality, and a qPCR result depends on the instrument in ways the operator cannot see: the uniformity of the thermal block, the accuracy of the temperature, the optical crosstalk between wells and the linearity of the detection all move the cycle threshold, and therefore the reported quantity. The standard sets the requirements on working conditions, appearance, safety, environmental adaptability, electromagnetic compatibility and performance, and the evaluation methods for each of them, with annexes giving the statistical method for judging a significant difference between two sets of data and the F and t distribution tables. It took effect on 1 December 2023.

This document specifies the requirements, evaluation methods and evaluation reports for real-time fluorescent quantitative PCR instruments: This document is applicable to the performance evaluation of real-time fluorescent quantitative PCR instruments, including fluorescent quantitative PCR instruments for medical clinical diagnosis and general analysis: Fluorescence quantitative PCR instrument was used for analysis: Refer to this document for other devices for quantitative or qualitative analysis of target nucleic acid fragments based on the principle of polymerase chain reaction implement:

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:

GB/T 11606 Environmental test methods for analytical instruments

GB/T 14710 Environmental requirements and test methods for medical electrical appliances GB/T 18268:

1 Electromagnetic Compatibility Requirements for Electrical Equipment for Measurement, Control and Laboratory Use Part 1: General Requirements GB/T 18268:

26 Electromagnetic Compatibility Requirements for Electrical Equipment for Measurement, Control and Laboratory Use Part 26: Particular Requirements for In Vitro Diagnostic (IVD) medical devices

GB/T 34065-2017 Safety requirements for analytical instruments

GB/T 34797 Quality technical requirements for nucleic acid primers and probes

GB/T 35542 TaqDNA polymerase

YY0648 Safety requirements for electrical equipment for measurement, control and laboratory use Part 2-101: In vitro diagnostic (IVD) medical equipment specific requirements for

3 Terms and Definitions

The following terms and definitions apply to this document: 3:

1 Based on the principle of polymerase chain reaction, the target nucleic acid fragments are amplified in vitro through the temperature change cycle program, and the An instrument for real-time acquisition and processing of fluorescent signals, and quantitative or qualitative analysis of target nucleic acid fragments: 3:

2 Ct valueCyclethresholdvalue The number of cycles experienced when the fluorescent signal in each PCR reaction tube reaches the set threshold: 3:

3 Constant temperature stage thermostaticprocess The average temperature of the hole position of the instrument reaches the set value (deviation within $\pm 0.5^{\circ}\text{C}$) and maintains the temperature for a period of time: