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GB/T 47026-2026

**Performance measurement method for rapid nucleic acid
detection instruments**

快速核酸检测仪性能的测定方法

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Table of Contents

1.Scope	1
2 Normative References	1
3.Terms and Definitions	1
4.Measurement conditions	2
5.Determination Methods	2
11 References	12

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 Ministry of Science and Technology of the People's Republic of China. This document is under the jurisdiction of the National Technical Committee on Standardization of Instrument Analysis and Testing (SAC/TC481). This document was drafted by: China Customs Science and Technology Research Center, Xi'an Jiaotong University, China National Institutes for Food and Drug Control, and Beijing Municipal Science and Technology Commission. Institute of Analytical and Testing Technology (Beijing Municipal Center for Physical and Chemical Analysis and Testing), Guangzhou Institute of Metrology and Testing Technology, Hebei Chemical and Pharmaceutical Vocational College Vocational and Technical College, Northeast Agricultural University, National Institute of Metrology, Chaoyang District Center for Disease Control and Prevention, Beijing, Jilin Provincial Product Quality Supervision Bureau Inspection and Testing Institute, China Academy of Testing Technology, Chengdu Institute of Metrology and Testing, China Agricultural University, Beijing Lindian Weiye Electronic Technology Co., Ltd. Company, Alashankou Customs Technology Center, Jilin Provincial Institute of Metrology, Yunnan Provincial Institute of Metrology and Testing Technology, Shenzhen Municipal Institute of Metrology and Quality Inspection Research Institute, China Inspection and Testing Southwest Metrology Co., Ltd., Binzhou Inspection and Testing Center, Hebei Provincial Institute of Metrology and Supervision, Shanxi International Travel Health Health Center (Taiyuan Customs Port Clinic), National Food and Strategic Reserves Administration Research Institute, Zhuhai International Travel Health Care Center (Gong Beijing Customs Port Clinic), Beijing Institute of Medical Device Testing (Beijing Medical Biological Protective

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1 Scope

GB/T 47026-2026 is the Chinese national standard covering the point-of-care PCR instrument - its limit of detection, its repeatability and cross-contamination between runs, the time to result and the temperature control that the chemistry depends on. First edition, in force since 1 March 2026, under the Ministry of Science and Technology. It was issued on 28 January 2026 and has been in force since 1 March 2026, as a first edition. The document is under the responsibility of the Ministry of Science and Technology. This page is published from the official record of the 2026 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 describes the method for determining the performance of rapid nucleic acid testing instruments. This document applies to the determination of performance indicators for various rapid nucleic acid testing instruments with temperature control functions. Other

nucleic acid testing instruments can use this document as a reference.

2 Normative references

This document has no normative references.

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 It integrates the entire process from sample processing to amplification and detection, and has nucleic acid extraction capabilities, or achieves nucleic acid release through chemical or other methods. This is a nucleic acid testing device designed to meet the needs of rapid and automated testing, with a total testing time of less than 1 hour.

3.2 Ct value Cyclethreshold value The number of cycles required for the fluorescence signal in each polymerase chain reaction (PCR) tube to reach a set threshold. [Source: GB/T 42753-2023, 3.2]

3.3 Thermostatic process The average temperature of the instrument orifice reaches the set value (within $\pm 0.5^{\circ}\text{C}$ deviation) and remains at that temperature for a period of time. [Source: GB/T 42753-2023, 3.3]

3.4 The temperature change range of the orifice during the constant temperature phase of the instrument. [Source: GB/T 42753-2023, 3.4]

3.5 During the instrument's constant temperature phase, the temperature consistency among the various well sites is maintained. [Source: GB/T 42753-2023, 3.5]

3.6 Consistency of repeated fluorescence intensity measurements at instrument wells under the same temperature and fluorescence conditions. [Source: GB/T 42753-2023, 3.6]

3.7 Under the same temperature and fluorescence conditions, the consistency of fluorescence intensity detection values among different wells of the instrument.