ICS 11.100.10
CCS C44

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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1918-2023

Digital polymerase chain reaction analysis system

数字聚合酶链反应分析系统

Issued on: September 5, 2023 **Implemented on: September 15, 2024**

Issued by: National Medical Products Administration

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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. Please note that some content in this document may be subject to patents. Release of this document The Agency assumes no responsibility for identifying patents. This document is proposed by the National Medical Products Administration. This document is under the jurisdiction of the National Standardization Technical Committee for Medical Clinical Laboratory and In Vitro Diagnostic Systems (SAC/TC136). This document was drafted by: Beijing Institute of Medical Device Inspection (Beijing Medical Biological Protection Equipment Inspection and Research Center), China Food Institute for Drug Control, Beijing Medical Device Evaluation and Inspection Center, Beijing Xinyi Biotechnology Co., Ltd., Guangdong Yongnuo Medical Technology Co., Ltd. Company, Bole Life Medical Products (Shanghai) Co., Ltd., Beijing Da Microbiology Technology Co., Ltd., Suzhou Sinafu Medical Technology Co., Ltd., Chongqing Geneshengzi Biotechnology Co., Ltd. The main drafters of this document. Li Da, Huang Jie, Zhou Haiwei, Sun Rong, Su Shisheng, Xu Shaofei, Wang Ruixia, Liu Jingwen, Fu Jun, Wu Kun, Yuan Chengbin. Digital polymerase chain reaction analysis system

1 Scope

YY/T 1918 is the Chinese standard for digital PCR analysis systems. Digital PCR partitions a sample into thousands of tiny reactions and counts how many contain target, which gives an absolute copy number without a standard curve and detects a rare variant against a large background of normal sequence. That makes it the technique behind circulating tumour DNA testing, minimal residual disease monitoring and non-invasive prenatal work. This document sets the requirements such a system has to meet and the test methods that verify them, covering partition uniformity, counting accuracy, the limit of detection, contamination control and the software that turns partition counts into a result. For a manufacturer of dPCR instruments, this is the document a Chinese registration is assessed against.

26.Special requirements In vitro diagnostic (IVD) medical equipment

2 Normative reference documents

The contents of the following documents constitute essential provisions of this document through normative references in the text. Among them, the dated quotations For undated referenced documents, only the version corresponding to that date applies to this document; for undated referenced documents, the latest version (including all amendments) applies to this document.

GB/T 191 Packaging, storage and transportation pictorial mark

GB 4793.1 Safety requirements for electrical equipment for measurement, control and laboratory use Part

GB/T 18268.26 Electromagnetic compatibility requirements for electrical equipment for measurement, control and laboratory use Part

GB/T 29791.3 Information provided by manufacturers of in vitro diagnostic medical devices (labeling) Part

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 Disperse nucleic acid samples into thousands of equal-volume reaction units, which contain 0, 1, or multiple nucleic acid molecules. polymerase chain reaction.

Note. An absolute quantification technology for nucleic acid molecules that does not require a standard curve, which can directly give the copy number of DNA or RNA molecules, which is the concentration of the starting nucleic acid sample. absolute quantification.

3.2 Instruments and equipment that implement digital polymerase chain reaction and data analysis processes. Specific steps include the generation of reaction units, polymerase chain reaction

6 Characteristics of laboratory material heating equipment Special requirements

GB 4793.9 Safety requirements for electrical equipment for measurement, control and laboratory use Part

9.Laboratory use for analysis and other purposes Special requirements for automatic and semi-automatic equipment

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