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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1908-2023

Nucleic acid extraction system

核酸提取仪

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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. The publisher of this document 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 Protective Equipment Inspection and Research Center), Shenzhen BGI Intelligent Technology Co., Ltd., China Institute for Food and Drug Control, Chinese Academy of Medical Sciences Peking Union Medical College Hospital, Capital Medical University Affiliated Beijing Tiantan Hospital, Hangzhou Bioer Technology Co., Ltd., Xi'an Tianlong Technology Co., Ltd., Shengxiang Biotechnology Co., Ltd., Shanghai Siludi Biomedical Technology Co., Ltd. and Kaijie Enterprise Management (Shanghai) Co., Ltd. The main drafters of this document. Li Da, Li Jing, Zhang Wenxin, Yi Jie, Zhang Guojun, Shang Xiaohui, Tian Zhen, Deng Zhongping, Liu Congzhi, Zhang Xi, Dai Leiying. Nucleic acid extraction instrument

1 Scope

YY/T 1908 is the Chinese standard for automated nucleic acid extraction systems, the instruments that isolate DNA and RNA from clinical samples ahead of PCR or sequencing. Extraction is the step where a molecular test most often fails: a poor yield, a carried-over inhibitor or cross-contamination between wells produces a result that looks valid and is not. This document sets the requirements such an instrument has to meet and the test methods that verify them, covering extraction yield and purity, reproducibility between positions, carryover contamination and the software controlling the run. Molecular testing capacity expanded enormously in China during the pandemic years and stayed, along with the instruments. For a manufacturer, 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 surfacemagneticflux-densitysurfacemagneticflux-density The density of magnetic field lines perpendicularly passing through unit area.

3.2 Temperature consistency between corresponding sample wells of the module. [Source: YY/T 1173-2010,3.9]

3.3 average heating ratemeanheatingrate The average temperature rise of the module per unit time during the heating process.

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