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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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Quality assessment requirements for SARS-CoV-2 nucleic acid detection reagents

新型冠状病毒核酸检测试剂盒质量评价要求

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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 of Standardization Documents" Drafting. Please note that some of the contents of this document may involve patents. The issuing agency of this document is not responsible for identifying patents. This document was proposed by the State Drug Administration. This document is under the jurisdiction of the National Medical Clinical Laboratory and In Vitro Diagnostic System Standardization Technical Committee (SAC/TC136). Drafting organizations of this document. China Institute for Food and Drug Control, Medical Device Technical Evaluation Center of the State Drug Administration, Beijing Medical Device Inspection Institute, Shenzhen Huada Yinyuan Pharmaceutical Technology Co., Ltd., Beijing Boao Jingdian Biotechnology Co., Ltd., Shanghai Jieno Biotech Co., Ltd. Technology Co., Ltd., Sun Yat-sen University Daan Gene Co., Ltd., Shengxiang Biotechnology Co., Ltd., Shanghai Fosun Long March Medical Science Co., Ltd. Limited company. The main drafters of this document. Liu Donglai, Zhou Haiwei, Dong Jinchun, Ma Tingting, Xu Tingying, Xu Sihong, Yang Zhen, Li Da, Wu Honglong, Liu Yingying, Cheng Tianling, Jiang Xiwen, Dai Lizhong, Xia Yi. Novel coronavirus nucleic acid detection kit Quality evaluation requirements

1 Scope

China's national quality assessment requirements for SARS-CoV-2 nucleic acid detection reagents. It specifies the quality evaluation requirements, the test methods, and the labels and instructions. Nucleic acid detection by reverse transcription PCR is the reference method against which every other test is judged, and its sensitivity is what gives it that position: it amplifies the target exponentially, so a handful of viral genomes in a sample produces a detectable signal. What has to be assessed is where that sensitivity ends and what it costs. The limit of detection has to be established against a quantified reference material rather than claimed. Specificity has to be shown against the coronaviruses and other respiratory pathogens that share sequence. And the design has to be robust to the

virus changing - a test targeting a single region can be defeated by mutation in that region, which is why multi-target designs became the norm and why the assessment has to consider it.

This document specifies the quality evaluation requirements, test methods, labels and instructions, packaging, and transportation of the new coronavirus nucleic acid detection kit And storage. This document is suitable for qualitative testing of throat swabs, nasopharyngeal swabs, alveolar lavage fluid, sputum, respiratory tract washing fluid, aspiration fluid or other respiratory components. Quality evaluation of the nucleic acid amplification detection kit for the new coronavirus nucleic acid in secretions and other samples.

Note. Nucleic acid amplification methods include polymerase chain reaction (PCR) technology and isothermal nucleic acid amplification technology.

2 Normative references

The content of the following documents constitutes an indispensable clause of this document through normative references in the text. Among them, dated quotations 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 191 Packaging, storage and transportation pictorial signs

GB/T 29791.2 Information provided by manufacturers of in vitro diagnostic medical devices (labeling) Part

3 Terms and definitions

There are no terms and definitions that need to be defined in this document.

4 Quality evaluation requirements

4.1 Appearance The appearance should meet but not limited to the following requirements.

a) All components of the kit are complete and complete, and there is no leakage of liquid;

b) The Chinese packaging label is clear and non-wearing.

4.2 Nucleic acid extraction and purification The performance of nucleic acid extraction and purification should meet the following requirements.

a) A kit containing nucleic acid extraction and purification components, the manufacturer's functions for nucleic acid extraction and purification, such as efficiency, purity, integrity, etc., Verify separately;

b) For kits that do not contain nucleic acid extraction components, the manufacturer's

instructions or designated extraction kits, and perform nucleic acid extraction and purification functions verify;

c) For kits that do not perform nucleic acid extraction and purification, but directly perform detection after nucleic acid lysis or release, the manufacturer cleavages nucleic acid Or release the function and verify the potential interference of the enzyme in the kit.