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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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Quality assessment requirements for SARS-CoV-2 total antibody detection reagents

新型冠状病毒抗体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, Chinese People's Liberation Army General Hospital, National Medical Products Administration Instrument Technology Evaluation Center, Beijing Medical Device Inspection Institute, Chongqing Public Health Medical Treatment Center, Guangzhou Wanfu Biotechnology Co., Ltd. Company, Shanghai Xinchao Biotechnology Co., Ltd., Beijing Wantai Biopharmaceutical Co., Ltd. The main drafters of this document. Xia Deju, Shi Dawei, Hu Jinjun, Xu Sihong, Yang Zhen, He Kunlun, Zhang Ying, Li Hongran, Bi Chunlei, Wang Jing, Kang Keren, Zhang Xiaoyan, Sun Xudong, Qiao Shan. Novel coronavirus antibody detection kit Quality evaluation requirements

1 Scope

China's national quality assessment requirements for SARS-CoV-2 total antibody detection reagents. It specifies the quality requirements, the test methods, and the labels and specifications. A total antibody test detects the immunoglobulin response without separating the classes, and it exists because the separation is often not what a user needs. For seroprevalence work the question is whether a person has been exposed at all, and a test that captures IgM, IgG and IgA together detects that earlier than IgG alone and more reliably than IgM alone. The design is usually a double-antigen sandwich, in which the viral antigen appears on both sides of the reaction so that only antibody binding both is detected

- which gives high specificity and detects any class. Assessing it means establishing that specificity against the cross-reacting endemic coronaviruses, and stating clearly what a positive result does and does not imply about immunity, which is where these tests were most often misread.

This document specifies the quality requirements, test methods, labels and specifications involved in the quality evaluation of new coronavirus (total) antibody detection kits. Instructions, packaging, transportation and storage. This document is suitable for the use of immunochromatography, enzyme-linked immunoassay and chemiluminescence method to detect the new type of coronavirus in human serum, plasma and whole blood. A kit for in vitro qualitative detection of virus-specific antibodies (including IgM, IgG and other antibody types).

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.

4.1 Physical properties

4.1.1 Appearance The appearance should at least conform to but not limited to.

a) The components of the kit should be complete and complete, and there should be no liquid leakage;

b) The packaging label should be clear and free from wear.

4.1.2 Film strip width The width of the film strip should not be less than 2.5mm.

Note. This clause only applies to immunochromatography.

4.1.3 Liquid moving speed The liquid moving speed should not be lower than 10mm/min.

Note. This clause only applies to immunochromatography.

4.2 Performance

4.2.1 Compliance rate of positive reference products When using a national positive reference product or a standardized positive reference product for testing, the results should meet the corresponding requirements.