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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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

新型冠状病毒IgM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 Review Center, Beijing Institute of Medical Device Inspection, Guangzhou Institute of Biomedicine and Health, Chinese Academy of Sciences, Innotek (Tangshan) Biology Technology Co., Ltd., Guangdong Hexin Health Technology Co., Ltd., Boose (Chongqing) Biotechnology Co., Ltd., Dana (Tianjin) Biotechnology Company limited by shares. The main drafters of this document. Shi Dawei, Xia Deju, Hu Jinjun, Xu Sihong, Yang Zhen, He Kunlun, Li Boan, Han Zhaozhao, Zhu Jinsheng, Feng Liqiang, Zhang Xiujie, Li Chenyang, Liu Ping, Zhou Zeqi. Novel coronavirus IgM antibody detection kit Quality evaluation requirements

1 Scope

China's national quality assessment requirements for SARS-CoV-2 IgM antibody detection reagents. It specifies the quality evaluation requirements, the test methods, and the labels and instructions. IgM is the antibody class produced first in an immune response, appearing days after infection and declining within weeks, and that timing is what an IgM test is for: it indicates recent rather than past exposure, and it was widely used alongside IgG to distinguish current from historical infection. Its assessment is the most demanding of the antibody tests, for two reasons. IgM is less specific than IgG by nature - the early antibody response is broadly reactive before it matures - so cross-reaction with other infections is

commoner. And its window is narrow, so the test's performance depends heavily on when in the illness the sample was taken, which means a sensitivity figure without a stated day post-onset is not interpretable.

This document specifies the quality evaluation requirements, test methods, labels and instructions, packages of the new coronavirus IgM antibody detection kit Loading, 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 IgM antibodies.

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.

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

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

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.