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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 40966-2021

Quality assessment requirements for SARS-CoV-2 antigen detection reagents

新型冠状病毒抗原检测试剂盒质量评价要求

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Table of Contents

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, Guangzhou Wanfu Biotechnology Co., Ltd., Beijing Kingwolf Bioengineering Technology Co., Ltd. The main drafters of this document. Zhou Haiwei, Liu Donglai, Ma Tingting, Xu Tingying, Xu Sihong, Yang Zhen, Xie Yi, Sun Li, Lu Xuewen, Yuan Jing. Novel coronavirus antigen detection kit Quality evaluation requirements

1 Scope

China's national quality assessment requirements for SARS-CoV-2 antigen detection reagents. It gives the quality evaluation requirements, the test methods, and the labels and instructions. An antigen test detects viral protein directly, gives a result in fifteen minutes without a laboratory, and can be performed by the person being tested - which is what made it the instrument of mass screening. Its limitation is inherent: it detects protein rather than amplifying nucleic acid, so it needs far more virus present to register, and it therefore identifies people at their most infectious while missing those at the start and end of an infection. Assessing such a test means quantifying that honestly - the limit of detection, the sensitivity against a nucleic acid reference at defined viral loads, the specificity against the other respiratory viruses that circulate, and the reproducibility in untrained hands, which is where a test that performs well in a laboratory can fail entirely.

This document gives the quality evaluation requirements, test methods, labels and instructions, packaging, and transportation of the new coronavirus antigen detection kit And storage. This document is applicable to upper respiratory tract samples such as throat swabs, nasal swabs, saliva, blood samples such as serum, plasma, and whole blood, as well as sputum and respiratory tract samples. Lower respiratory tract samples such as suction tract, bronchial lavage fluid, and alveolar lavage fluid are the new coronavirus antigen detection kits for testing samples. Quality Evaluation.

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 29791.1 Information provided by manufacturers of in vitro diagnostic medical devices (labeling) Part

3 Terms and definitions

The terms and definitions defined in GB/T 29791.1 apply to this document.

4.1 Physical properties

4.1.1 Appearance The components of the kit should be complete and complete, and there should be no liquid leakage; the packaging label should be clear and easy to identify.

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.