ICS 11.100.10
CCS C 44

NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 40983-2021

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

新型冠状病毒IgG抗体检测试剂盒质量评价要求

Issued on: November 26, 2021 **Implemented on: March 1, 2022**

Issued by: State Administration for Market Regulation;
Standardization Administration of the PRC

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, Chinese People's Liberation Army General Hospital, National Medical Products Administration Instrument Technology Evaluation Center, Beijing Institute of Medical Device Inspection, Institute of Pathogenic Biology, Chinese Academy of Medical Sciences, Zhuhai Lizhu Reagent Co., Ltd. The company, Boo Saisi (Chongqing) Biotechnology Co., Ltd., and Dana (Tianjin) Biotechnology Co., Ltd. The main drafters of this document. Shi Dawei, Xia Deju, Hu Jinjun, Xu Sihong, Yang Zhen, He Kunlun, Zhang Chunyan, Chen Tingting, Dai Leiying, Ren Lili, Dai Junying, Liu Ping, Zhou Zeqi. Novel coronavirus IgG antibody detection kit Quality evaluation requirements

1 Scope

China's national quality assessment requirements for SARS-CoV-2 IgG antibody detection reagents. It specifies the quality evaluation requirements, the test methods, and the labels and instructions. An IgG antibody test answers a different question from a viral test: not whether someone is infected now, but whether their immune system has responded to the virus at some point in the past. IgG appears one to three weeks after infection and persists, which makes it useless for diagnosis and valuable for seroprevalence surveys, for assessing vaccine response, and for selecting convalescent plasma donors. Assessing such a reagent has its own difficulties. Specificity is the hard part, because antibodies

against the endemic seasonal coronaviruses cross-react, and a test with ninety-nine per cent specificity applied in a population with two per cent true prevalence produces more false positives than true ones - a fact that has to be stated in the instructions rather than left to the user.

This document specifies the quality evaluation requirements, test methods, labels and instructions, packages of the new coronavirus IgG 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 IgG 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.

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 following requirements.