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Quality assessment requirements for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) total antibody detection kit

新型冠状病毒抗体检测试剂盒质量评价要求

(征求意见稿）

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FOREWORD

SAC/TC 136, Clinical Laboratory Testing and Invitro Diagnostic Test Systems is in charge of this English translation, the Chinese original shall be considered authoritative.

This document is drafted in accordance with the rules given in GB/T 1.1-2020 *Directives for standardization - Part 1: Rules for the structure and drafting of standardizing documents.*

Please note that some contents in this document might refer to some patents. The issuing authority of this document is not responsible for identifying such patents.

This document was proposed by National Medical Products Administration.

This document was prepared by SAC/TC 136.

Quality Assessment Requirements for Severe Acute Respiratory Syndrome Coronavirus 2(SARS-CoV-2) total antibody Detection Kit

1. Scope

This document specifies the requirements for quality assessment, test method, labeling, instructions for use, package, transportation, and storage of total antibody detection kit for SARS-CoV-2.

This document is applicable to the kit for in vitro qualitative detection of novel coronavirus specific antibodies (including IgM, IgG and other types of antibodies) in human serum, plasma and whole blood based on the principles of immunochromatography, enzyme-linked immunosorbent assay and chemiluminescence.

2. Normative References

The following documents are indispensable for application of this document. For dated references, only the edition cited is applied. For undated references, the latest edition of the referenced document (including all amendments) was applied.

GB/T 191 *Packaging - Pictorial Marking for Handling of Goods*

GB/T 29791.2 *In Vitro Diagnostic Medical Devices - Information Supplied by the Manufacturer (Labelling) - Part 2: In Vitro Diagnostic Reagents for Professional Use*

3. Terms and Definitions

No terms or definitions need to be defined in this document.

4. Quality Assessment Requirements

4.1 Physical security

4.1.1 Appearance

The appearance should at least comply with but not limited to:

a) The components of the reagent kit should be without defect and complete, with no liquid leakage;

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

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 migration speed

The liquid migration speed should not be less than 10mm/min.

Note: This clause only applies to immunochromatography.

4.2 Properies

4.2.1 Coincidence Rate of Positive References

When using national positive reference materials or standardized positive reference materials for testing, the results should meet the corresponding requirements.

Standardized positive reference materials should include 5 novel coronavirus IgM antibody positive samples and 5 novel coronavirus IgG antibody positive samples from different sources, and show different titer levels.

Note: See Appendix A for information on National Reference Panel positive samples in this document.

4.2.2 Coincidence Rate of Negative References

When using national negative reference materials or standardized reference materials for testing, the results should meet the corresponding requirements.

The standardized negative reference materials should at least include normal clinical samples, samples containing Confounding such as Rheumatoid factor and other pathogen specific antibody positive samples. Pathogen specific antibody positive samples should include coronavirus (HKU1, OC43, NL63, 229E), influenza virus, Enterovirus, respiratory syncytial virus, and adenovirus antibody positive samples.

Note: See Appendix A for information on the National Reference Panel negative samples in this document.

4.2.3 Limit of Detection (LoD)

The results of testing using national LoD reference materials or standardized LoD reference materials should meet the corresponding requirements.

The standardized LoD reference materials can be a series of diluted samples and include the detection limit level.

Note: See Appendix A for information on the National Reference Panel sensitivity sample in this document.

4.2.4 Repeatability or (intra batch) precision

When using national precision reference materials or standardized precision reference materials for testing, the results should meet the following requirements:

a) For the reagent kit of colloidal gold immunochromatography, the results should be all positive and the band color should be uniform;

b) For the fluorescent immunochromatography kit, the results should all be positive;

c) For ELISA and chemiluminescence kits, both results should be positive, and the coefficient of variation (CV,%) of the measured value or the ratio of the measured value to the positive judgment value should not exceed 15.0%.

Note1: Measurement values include but are not limited to absorbance values, luminescence values, or concentration values.

Note2: See Appendix A for information on the National Reference Panel precision sample in this document.

4.2.5 Inter batch difference or inter batch precision

When using national precision reference materials or standardized precision reference materials for testing, the results should all be positive, and the coefficient of variation (CV,%) of the measured value or the ratio of the measured value to the positive judgment value should not exceed 15.0%.

Note1: Measurement values include but are not limited to absorbance values, luminescence values, or concentration values.

Note2: See Appendix A for information on the National Reference Panel precision sample in this document.

Note3: This clause only applies to enzyme-linked immunosorbent assay and chemiluminescence assay.

4.2.6 Stability

The kit should be validated using the following methods.

a) Shelf life stability: The manufacturer should specify the shelf life of the kit. Under the storage conditions claimed by the manufacturer, the kits near expiration should be used to perform the test in 4.2.1~4.2.4, the results should

meet the corresponding requirements.

b) Thermal stability test: Test 4.2.1~4.2.4 under the thermal stability test conditions specified by the manufacturer, and the results should meet the corresponding requirements.

Note 1: Thermal stability test results should not be used directly to determine the shelf life of the kit unless the derivation formula used is based on extensive stability study data.

Note 2: Any combination of a) and b) methods can be selected depending on the product characteristics, but the method selected should be capable of validating the stability of the product to ensure that the performance meets the standard requirements during the shelf life.

5. Test Method

5.1 Physical security

5.1.1 Appearance

Visually inspect under natural light with normal or corrected vision.

5.1.2 Film strip width

Measure the width of the film strip using a universal measuring tool according to the manufacturer's specified method.

5.1.3 Liquid migration speed

Measure the liquid travel distance and time using a universal measuring tool and a stopwatch according to the manufacturer's prescribed method, and then calculate the liquid travel speed.

5.2 Properies

5.2.1 Coincidence Rate of Positive References

Follow the instructions of the reagent kit to test national positive reference materials or standardized positive reference materials.

Note: See Appendix A for information on National Reference Panel positive samples in this document.

5.2.2 Coincidence Rate of Negative References

Follow the instructions of the reagent kit to test national negative reference materials or standardized negative reference materials.

Note: See Appendix A for information on the National Reference Panel negative samples in this document.

5.2.3 Limit of Detection (LoD)

Follow the instructions of the reagent kit to test national LoD reference materials or standardized LoD reference materials .

Note: See Appendix A for information on the National Reference Panel sensitivity sample in this document.

5.2.4 Repeatability or (intra batch) precision

Take one batch of reagent kit and follow the instructions of the kit to conduct 10 repeated tests on national precision reference materials or standardized precision reference materials. For ELISA and chemiluminescence kits, the coefficient of variation (CV,%) of the measured values from 10 test results should also be calculated.

Note1: Measurement values include but are not limited to absorbance values, luminescence values, or concentration values.

Note2: See Appendix A for information on the National Reference Panel precision sample in this document.

5.2.5 Inter batch difference or inter batch precision

Take 3 batches of reagent kits and operate according to the instructions of the kit. Perform 10 repeated tests on national precision reference materials or standardized precision reference materials for each batch, and calculate the coefficient of variation (CV,%) of the measured values of the 30 test results.

Note1: Measurement values include but are not limited to absorbance values, luminescence values, or concentration values.

Note2: See Appendix A for information on the National Reference Panel precision sample in this document.

5.2.6 Stability

One or both of the following methods can be used for validation:

a) Validity stability: Under the storage conditions specified by the manufacturer, take a reagent kit that is close to or has expired for a certain period of time and test it according to 5.2.1-5.2.4;

b) Thermal stability: Under the thermal stability test conditions specified by the manufacturer, take the reagent kit within the validity period and conduct testing according to 5.2.1-5.2.4.

6. Labels and Instructions for Use

In compliance with the provisions in GB/T 29791.2.

7. Package, Transportation and Storage

7.1 Package

The pictorial marking for handling of goods should meet the requirement of GB/T 191. The packaging container should be well sealed, complete, and free from leakage and damage.

7.2 Transportation

Detection kits should be shipped according to the manufacturer’ s requirements. During transportation, they should be protected from moisture, excessive pressure, direct sunlight rain and snow, contact with acidic and alkaline substances, and damage to the internal and external packaging.

7.3 Storage

The kits should be stored under the conditions specified by the manufacturer.

Appendix A

(Informative)

Information on National Reference Panel for 2019-nCoV (SARS-CoV-2) antibody Detection Kit

A.1 Description

This appendix provides the information national reference applicable in Chapter 4 of this document. The national references are "National Reference materials for novel coronavirus IgM Antibody Test Reagent" (Reference No. 370096), "National Reference for novel coronavirus IgG Antibody Test Reagent" (Reference No. 370097) "National Reference for novel coronavirus IgM Antibody Test Reagent (ELISA/Chemiluminescence)" (Reference No. 370093) and "National Reference for novel coronavirus IgG Antibody Test Reagent (ELISA/Chemiluminescence)" (Reference No. 370094).

A.2 Usage

The "National Reference materials for novel coronavirus IgM Antibody Detection Reagents" and "National Reference for novel coronavirus IgG Antibody Detection Reagents" are respectively applicable to the quality evaluation of novel coronavirus IgM and IgG antibody detection reagents for immunochromatography.

The "National Reference materials for novel coronavirus IgM Antibody Detection Reagent (ELISA/Chemiluminescence)" and the "National Reference materials for novel coronavirus IgG Antibody Detection Reagent (ELISA/Chemiluminescence)" are respectively applicable to the quality evaluation of novel coronavirus IgM and IgG antibody detection reagents for ELISA and chemiluminescence.

A.3 Specification and Components

The specification and components of National Reference Panel are shown in Table A.1.

Table A.1 Specification and Composition of National Reference Materials

Type	No.	Specimens	Size μL/vial
Negative	N1	Influenza A virus IgM positive plasma	50
	N2	IgM positive plasma of influenza A and Influenza B virus	
	N3	Influenza A virus IgM positive plasma	
	N4、N5	Legionella pneumophila IgM positive plasma	
	N6、N7	Chlamydia pneumoniae IgM positive plasma	
	N8	Rheumatoid factor serum	
	N9~N11	Mycoplasma pneumoniae IgM positive plasma	
	N12	Adenovirus IgM positive plasma	
	N13~N14	Respiratory syncytial virus IgM positive plasma	
	N15	Parainfluenza virus IgM positive plasma	
	N16、N17	Chlamydia pneumoniae IgG positive plasma	
	N18	Measles morbillivirus IgG positive plasma	
	N19	Mumps virus IgG positive plasma	
	N20~N25	Normal human plasma	
Positive	P1~P10	Inactivated serum/plasma of patients with novel coronavirus pneumonia	50
Limit of Detection	S		100
Precision	R		500
Matrix plasma	S0	Normal human plasma	500

A.4 Others

The current national reference materials manual can be searched and downloaded from the website of the distribution unit of the national reference. Part of the content of the national reference materials manual will be changed based on the batch of the reference materials.

References

[1] YY/T1579-2018 Stability Evaluation of In Vitro Diagnostic Medical Devices and in Vitro Diagnostic Reagents

[2] Key Points for Technical Review of 2019 novel coronavirus Antigen/Antibody Test Reagent Registration (Trial)