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

## 新型冠状病毒 IgG 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) IgG antibody Detection Kit

## 1. Scope

This document specifies the quality assessment requirements, test methods, labels and instructions, packaging, transportation and storage of SARS-CoV-2 IgG antibody test kit.

This document is applicable to the kit for in vitro qualitative detection of novel coronavirus specific IgG 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, coincidence rate of positive references should meet the following requirements:

a) For the reagent kit of immunochromatography, coincidence rate of positive references should not exceed 90%.

b) For ELISA and chemiluminescence kits, coincidence rate of positive references should be 100%.

Standardized positive reference materials should include 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, coincidence rate of negative references should not exceed 96%.

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)

When using national LoD reference materials or standardized LoD reference materials for testing, the results of national reference materials should be positive for L1 (reference material number: 370097) or positive for L1 and L2 (reference material number: 370094), and the rest should be positive or negative. The results of standardized LoD reference materials should not be lower than the requirements of the national reference materials.

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

Any combination of the following methods can be selected according to the product's property, but the selected method should be able to verify the stability of the product to ensure that its performance to meet the requirements before the expiration date:

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:** 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.

## 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 for 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 the 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 nationalLoD 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 Package 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) IgG antibody Detection Kit

### A.1 Description

This appendix provides information of national reference materials applicable in Chapter 4 of this document. The national reference materials are the " National Reference Materials for SARS-COV-2 IgG Antibody Test Reagent " (reference number: 370097) and the " National Reference Materials for SARS-COV-2 IgG Antibody Test Reagent" (Enzyme immunoassay/chemiluminescence method) " (Reference Number: 370094).

### A.2 Usage

The " National Reference Materials for SARS-COV-2 IgG Antibody Test Reagent" is applicable to the quality assessment of SARS-COV-2 IgG antibody test reagents by immunochromatography.

The " National Reference Materials for SARS-COV-2 IgG antibody test reagent (enzyme immunoassay/chemiluminescence method)" is applicable to the quality assessment of SARS-COV-2 IgG antibody test reagents by enzyme-linked immunoassay 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<br>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 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)