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# National Standard of the People's Republic of China

GB/T 40966—2021

# Quality assessment requirements for severe acute respiratory syndrome coronavirus 2 （SARS-CoV-2） antigen detection kit

## 新型冠状病毒抗原检测试剂盒质量评价要求

（征求意见稿）

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# FOREWORD

SAT/TC136 is in charge of this English translation. In case of any doubt about the contents of English translation, the Chinese original shall be considered authoritative.

This standard is drafted in accordance with the rules given in the GB/T 1.1-2020 Directives for standardization - Part 1: Structure and drafting of standards.

Attention is drawn to the possibility that some of the elements of this standard may be the subject of patent rights. The issuing body of this document shall not be held responsible for identifying any or all such patent rights.

This standard was proposed by National Medical Products Administration.

This standard was prpared by SAC/TC136 (National Medical Clinical Laboratory and In Vitro Diagnostic System Standardization Technical Committee).

# Quality assessment requirements for severe acute respiratory syndrome coronavirus 2 （SARS-CoV-2）antigen detection kit

## 1 SCOPE

This standard specifies the quality evaluation requirements, test methods, labels and instructions, packaging, transportation and storage of the SARS-CoV-2 antigen detection kit (hereinafter referred to as “the kit”).

This standard is applicable to kits which use oropharyngeal swabs, nasopharyngeal swabs, saliva and other upper respiratory tract samples, blood samples such as serum, plasma and whole blood, as well as sputum, respiratory tract aspirates, bronchial lavage fluid, lung alveolar lavage fluid, and other lower respiratory tract samples as testing sample.

## 2 Normative References

The following referenced documents contain provisions which, through reference in this text, constitue indispensable provisions of this standard. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including all amendments) applies.

GB/T 191 Packaging-Pictorial marking for handling of goods

GB/T 29791.1 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements

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

GB/T 29791.1 Defined terms and definitions apply to this document

## 4 Quality Assessment Requirements

4.1 Physical properties

4.1.1 Appearance

Each component of the kit shall be complete and without liquid leakage. The packaging label shall be clear and easy to identify.

4.1.2 Test strip width

The width of the test strip shall not be less than 2.5 mm.

Note: This clause only applies to immunochromatography.

4.1.3 Liquid migration rate

The liquid migratioin rate shall not be less than 10 mm/min.

Note: This clause only applies to immunochromatography.

4.2 Performance

4.2.1 Positive percent agreement

Tested with national reference or standardized reference, the kit shall meet a positive percent agreement of 100%.

The standardized positive reference shall meet the following requirements:

a) Positive reference materials should include at least 5 positive clinical samples or isolated cultures from different sources with temporal and regional characteristics;

b) Psitive reference should cover different concentration levels such as weak positive, moderate positive, and strong positive;

c) Inactivation method that meets the requirements of the kit should be used during preparation.

Note: See Annex A for information about national reference materials.

4.2.2 Negative percent agreement

Tested with national reference or standardized reference, the kit shall meet a negative percent agreement of 100%.

The standardized negative reference shall meet the following requirements:

a) The negative reference shall include pathogen types no less than those from the national

reference. Negative reference may be selected from the following pathogen types:

1) Common respiratory pathogens: H1N1, H3N2, H5N1, H7N9, influenza B virus, respiratory syncytial virus, parainfluenza virus, rhinovirus, adenovirus, enterovirus, human metapneumovirus, Mycoplasma pneumoniae, *Legionella* , *Bacillus pertussis*, *Haemophilus influenzae*, *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Klebsiella pneumonia*, etc.;

2) Other coronaviruses (HKU1, OC43, NL63, 229E, SARS coronavirus, MERS coronavirus);

3) Respiratory samples of normal people;

b) It is recommended that the standardized negative reference be verified at the medically relevant level of viruses or bacteria infections. For example, the level of bacterial infection is usually $1\times10^6$ CFU (colony forming unit)/mL or higher, and for viral infection, the level should be $1\times10^5$ PFU (plaque forming unit)/mL or higher;

c) Inactivation method that meets the requirements of the kit shall be used during preparation.

Note: See Annex A for information about national reference materials.

4.2.3 Detection limit

Tested with national reference or standardized reference, the kit shall meet its claimed detection limit.

The standardized detection limit reference shall meet the following requirements:

a) The detection limit reference shall use isolated culture;

b) The virus concentration unit should be $TCID_{50}$ (half tissue cell infection) or PFU (plaque forming unit);

c) Inactivation method that meets the requirements of the kit should be used during preparation.

Note: See Annex A for information about national reference materials.

4.2.4 Precision

Tested with national reference or standardized reference, the kit shall meet corresponding requirements.

Standardized precision reference shall meet the following requirements:

a) The precision reference shall be positive clinical samples or isolated cultures,

b) At least two levels of positive reference (weak positive, and moderate positive or strong positive) shall be set; the concentration of weak positive should be 1.5 to 4 times the concentration of the kit’s detection limit;

c) Inactivation method that meets the requirements of the kit should be used during preparation (if applicable).

Note: See Annex A for information about national reference materials.

4.2.5 Stability

The following methods may be used for verification:

a) Stability within validity period: Manufacturer shall specify the validity period of the kit. The tested kit shall be under the storage conditions specified by manufacturer and is near expiration date or beyond the expiration date. The tested kit shall meet corresponding requirements as specified in 4.2.1~4.2.4.

b) Thermal stability: The tested kit shall be under the thermal stability test conditions specified by manufacturer. The tested kit shall meet corresponding requirements as specified in 4.2.1~4.2.4.

Note 1: Thermal stability cannot directly infer the expiration date of the product, unless being applied to an empirical formula based on a large amount of stability research data.

Note 2: Any combination of a) and b) methods can be selected according to the product characteristics, but the selected method should be able to verify the stability of the product to ensure that the product performance meets the standard requirements during the validity period.

4.2.6 Inter batch difference

Tested with national reference or standardized reference, the kit shall meet corresponding requirements.

Standardized precision reference shall meet the following requirements:

a) The precision reference shall be positive clinical samples or isolated cultures,

b) At least two levels of positive reference (weak positive, and moderate positive or strong positive) shall be set; the concentration of weak positive should be 1.5 to 4 times the concentration of the kit’s detection limit;

c) Inactivation method that meets the requirements of the kit should be used during preparation (if applicable).

Note: See Annex A for information about national reference materials.

## 5 Test method

### 5.1 Physical properties

#### 5.1.1 Appearance

Visual inspection with normal vision or corrected vision under natural light.

#### 5.1.2 Test strip width

Use general measuring tools to measure the width of the test strip in accordance with the method specified by the manufacturer.

#### 5.1.3 Liquid migration rate

Use general measuring tools and stopwatch to measure the distance and time of liquid migration according to the method specified by the manufacturer, and calculate liquid migration rate.

### 5.2 Performance

#### 5.2.1 Positive percent agreement

Test the kit with national positive reference or standardized positive reference. Operate according to product instructions.

#### 5.2.2 Negative percent agreement

Test the kit with national negative reference or standardized negative reference. Operate according to product instructions.

#### 5.2.3 Detection limit

Test the kit with national detection limit reference or standardized detection limit reference. Operate according to product instructions.

5.2.4 Precision

Test the kit with national precision reference or standardized precision reference. Operate according to product instructions.

5.2.5 Stability

One or two of the following methods may be chosen for verification:

a) Stability within validity period: The tested kit shall be put at storage condition until near expiration date or beyond the expiration date. Test the kit according to requirements specified in 4.2.1~4.2.4. Operate according to product instructions.

b) Thermal stability: The tested kit shall be put at thermal stability test conditions specified by manufacturer. Test the kit according to requirements specified in 4.2.1~4.2.4. Operate according to product instructions.

6 Label and instructions for use

Shall meet the requirements of GB/T 29791.2.

7 Packaging, transportation and storage

7.1 Packaging

The packaging, storage and transportation signs shall meet the requirements as specified in GB/T 191. The packaging container shall ensure good sealing, completeness, no leakage and no damage.

7.2 Transportation

The kit should be transported as required by the manufacturer. During transportation, it should be moisture-proof, prevented from being piled up, avoid direct sunlight,rain and snow, prevented from contacting with acid and alkali substances, and prevented from damage to the inner and outer packaging.

7.3 Storage

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

Annex A

(annex informative)

Information of SARS-CoV-2 antigen detection reagent national reference

## A.1 Overview

The annex provides information about national reference applicable in Chapter 4 of this document. The national reference is the "SARS-CoV-2 Antigen Detection Reagent National Reference Material" (reference number: 370095).

## A.2 Purpose

The raw materials of the reference are SARS-CoV-2 cultures and other respiratory pathogen cultures. The reference is prepared by diluting raw materials with general buffer solution containing phosphate buffer, serum albumin (about 1%), trehalose (or sucrose, lactose, 5%) and gelatin (or gelatin hydrolyzed, dextran, 1%). It is suitable for quality control and evaluation of SARS-CoV-2 antigen detection reagents (including but not limited to colloidal gold method, immunofluorescence method, chemiluminescence method, etc.).

## A.3 Composition and specifications

The composition and specifications of the reference are shown in Table A.1.

Table A.1 Reference product composition and specifications

| Reference type | Reference number | Pathogen type | Specification |
|---|---|---|---|
| Negative reference | N1 | *Staphylococcus aureus* | 0.5 mL/piece |
| | N2 | *Streptococcus pneumoniae* | 0.5 mL/piece |
| | N3 | Measles virus | 0.5 mL/piece |
| | N4 | Mumps virus | 0.5 mL/piece |
| | N5 | Adenovirus type 3 | 0.5 mL/piece |
| | N6 | Mycoplasma pneumoniae | 0.5 mL/piece |
| | N7 | Parainfluenza type 2 | 0.5 mL/piece |
| | N8 | Metapneumovirus | 0.5 mL/piece |
| | N9 | Coronavirus OC43 | 0.5 mL/piece |
| | N10 | Coronavirus 229E | 0.5 mL/piece |
| | N11 | *Bacillus parapertussis* | 0.5 mL/piece |
| | N12 | Influenza B virus (Victoria line) | 0.5 mL/piece |
| | N13 | Influenza B virus (Yamagata series) | 0.5 mL/piece |
| | N14 | H1N1 (2009) influenza virus | 0.5 mL/piece |
| | N15 | Influenza A H3N2 virus | 0.5 mL/piece |
| | N16 | Avian influenza virus H7N9 | 0.5 mL/piece |
| | N17 | Avian influenza virus H5N1 | 0.5 mL/piece |
| | N18 | Epstein-Barr virus | 0.5 mL/piece |

| | | | |
|---|---|---|---|
| | N19 | Enterovirus CA16 | 0.5 mL/piece |
| | N20 | Rhinovirus | 0.5 mL/piece |
| Positive reference | P1 | SARS-CoV-2 | 0.5 mL/piece |
| | P2 | SARS-CoV-2 | 0.5 mL/piece |
| | P3 | SARS-CoV-2 | 0.5 mL/piece |
| | P4 | SARS-CoV-2 | 0.5 mL/piece |
| | P5 | SARS-CoV-2 | 0.5 mL/piece |
| | P6 | SARS-CoV-2 | 0.5 mL/piece |
| | P7 | SARS-CoV-2 | 0.5 mL/piece |
| | P8 | SARS-CoV-2 | 0.5 mL/piece |
| Detection limit | S | SARS-CoV-2 | 0.5 mL/piece |
| Precision | R | SARS-CoV-2 | 0.5 mL/piece |

A.4 Notes

The current national reference manual can be inquired and downloaded on the website of the distributor of the national reference. Part of the content of the national reference product manual will be changed according to the batch of the reference product.

Bibliography

[1] YY/T 1579-2018 *In Vitro Diagnostic Medical Devices Evaluation of the Stability of In Vitro Diagnostic Reagents.*

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**Technical Requirements for Single-use Protective Clothing for Medical Use**
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