# COVID-19 Antigen Sealing Tube Test Strip (Colloidal Gold)

AMAZING BIO

**Instructions for Use**

CE IVD REF

**In Vitro Diagnosis**
**For Professional Use**

**AB00101**

## INTENDED USE

Amazing COVID-19 Antigen Sealing Tube Test Strip is a lateral flow immunochromato-graphic assay for in vitro qualitative detection of COVID-19 nucleocapsid protein antigen in human oropharyngeal, nasal secretion, saliva specimens directly collected from individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset. Results from the Amazing COVID-19 Antigen Sealing Tube Test Strip should not be used as the sole basis for diagnosis.The kit is as an assistance for diagnostic and epidemiological investigation.The test strip is in a sealing tube to avoid potential biosecurity substances such as coronavirus from clinical sample .which will much help to avoid pathogen contamination and spreading to the operator and its environment. The kit is intended for use by medical professionals or trained operators who are proficient in performing tests and trained clinical laboratory personnel or individuals trained in point of care settings.

## SUMMARY

Coronavirus disease (COVID-19) is an infectious disease caused by a newly discovered coronavirus. Due to its highly contagious nature and global health crises, COVID-19 has been designated as a pandemic by the World Health Organization (WHO). COVID-19 continues to have devastating impacts on healthcare systems and the world economy including the U.S. To effectively end the COVID-19 pandemic, systematic screening and detection of both clinical and asymptomatic COVID-19 cases is critical. Particularly, the identification of subclinical or asymptomatic cases are important to reduce or stop the infection because these individuals may transmit the virus. As a point-of-care test with a 15 min testing time, Amazing COVID-19 Antigen Sealing Tube Test Strip allows effective screening of COVID-19 infection on a massive scale.

## PRINCIPLE

Amazing COVID-19 Antigen Sealing Tube Test Strip is based on sandwich lateral flow immunochromatographic assay highly sensitively detecting COVID-19 nucleocapsid protein in human oropharyngeal, nasal secretion, saliva specimens, having an invisible T (test) zone and C (control) zone. When sample is applied into the test tube, the liquid will laterally flow on the surface of the test strip. If there is enough COVID-19 antigen in the sample, a visible T band will appear. The C band should always appear after a sample is applied, indicating a valid result. By this means, the device can accurately indicate the presence of COVID-19 antigen in the sample.

## REAGENTS AND MATERIALS PROVIDED

**V.B: (Test with sealed buffer)**

1. Sealing tube test strip with sealed diluent
2. Sample swab
3. One instruction for use
4. Reference card

## PACKING SPECIFICATION

V.B: 20 kits X 1 pouch/box
V.D: 2 kits X 1 pouch/box
V.E: 1 kit X 1 pouch /box

## PRECAUTIONS

1. For in vitro diagnostic use only.
2. Do not use the kit beyond its expiration date.
3. Do not mix components from kits with different lot numbers.
4. Avoid microbial contamination of reagents.
5. Open foil pouch to take the first tube out, please seal the pouch carefully if there are other tubes left inside and use all tubes up within one week. The sealing tube test strip needs be used in 0.5 hour after taking out from aluminum foil to prevent detection failure due to moisture absorption.
6. Technician engaged in the collection of COVID-19 detection specimens should have biosafety training (qualified training) and corresponding experimental skills.
7. If positive result, the test card should be properly handled.

## STORAGE

The kit can be stored at room temperature (4-30°C). It is stable through the expiration date (18 months) marked on the foil pouch. Please seal the pouch carefully if batch tube still left inside and should use it up in one week once the pouch is opened. .DO NOT FREEZE. Do not store the test kit in direct sunlight.

## PREPARATION OF SAMPLE

The kit can be used for the detection of COVID-19 Antigen in oropharyngeal swabs, nasal swabs, saliva swabs specimens. Use the sample as soon as possible after collection. Because both the sample and strip chamber is within the tube, once the sample solution is added into the tube, the test should be carried out within 30 minutes to avoid air humidity affecting test strip performance.

**Sample collection**

**(1) Oropharyngeal Swab Sample**

a) Remove a oropharyngeal swab from the package.
b) Place the swab into the patient's mouth until it reaches the posterior; keep insert until resistance is encountered or the distance
c) Slowly and gently make one rotation of the swab over the surface of the posterior oropharyngeal (to prevent reflex cough, stop for one minute).
d) Slowly remove the swab from the nostril.

**(2) Nasal Swab Sample**

a) Remove a nasal swab from the package.
b) Place the swab into the patient's nostrils until it reaches the turbinates (less than one inch into the nostril).
c) Gently rotate 5 times the swab or more over the surface of the nasal.
d) Slowly remove the swab from the nostril while rotating it.
e) Repeat sample collection using the same swab in another nostril.

**(3) Saliva Swab Sample**

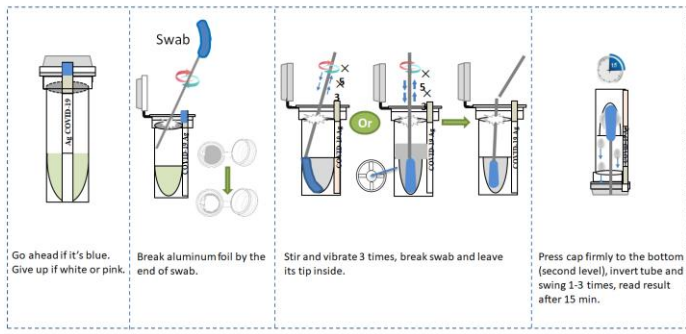
a) Remove a saliva swab from the package.
b) Place the swab into the patient's mouth as comfortable and and rub along the lower gums (see close up image) in a back and forth motion. Gently rub the gums 10 times. If possible, avoid rubbing the teeth.
c) Gently repeat rubbing motion on the opposite side of the mouth along the lower gums for an additional 10 times.
d) Slowly remove the swab from the mouth.

## TEST PROCEDURE

**V.B package**

1. Take out the kit and equilibrate to room temperature (20~25°C).
2. Open the foil pouch, take needed sealing tube test strips for test and seal the pouch carefully if batch tube is still left inside. Please use it up in one week once the pouch is opened. Write the patient's ID on the tube if required..
3. Carefully observe the top of the strip from outside, if the sensing paper changes to pink or white, please throw the test away; if it remains blue, go to next step.
4. Remove the desiccant cube and break the aluminum film with the end of the swab.
5. Insert the sampling swab into the tube, stir and vibrate 3 times, break swab and leave its tip inside.
6. Close and press the tube cap firmly to the bottom(second level), invert tube and swing 1-3 times to make sure all the liquid fall into the cap bottom, put it upside down on the flat bench.
7. Interpret the result after 15 minutes referring to the Reference card. (The strip in this creative sealing tube can avoid false signal caused by back migration of strip in the cassette).

**COVID-19 Antigen Sealing Tube Test Strip (Test Procedure) –V.B**




Note: The top of the strip contains humidity indicator, blue color indicates the strip is dry enough and available; but pink or white color indicates the strip is wet and not available.

## INTERPRETATION OF RESULT

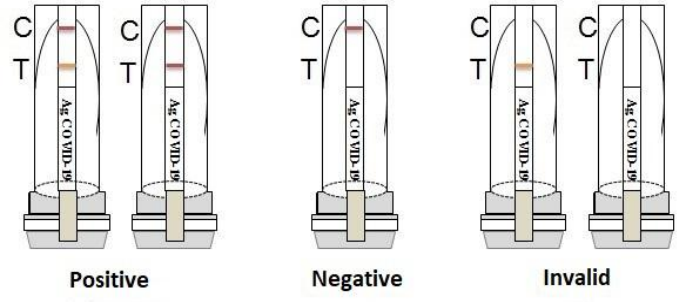
**Please interpret the result referring to the Reference card.**

**Positive**: The presence of both C band and T band, no matter T band is clear or vague, which means that COVID-19 antigen was detected.

**Note:** If T band is light gray, not red, it is a suspicious result, please retest days later or see a doctor.

**Negative**: Only clear C band appears, which means no COVID-19 antigen was detected.

**Invalid**: No colored band appears in C zone, no matter whether T band appears. It is necessary to retest with a new tube test strip.




## LIMITATIONS

• The kit can detect both viable (live) and non-viable, SARS-CoV and COVID-19. Test performance depends on the amount of virus (antigen) in the sample.
• Negative result may occur if the level of antigen in a sample is below the LOD of the test.
• Please strictly adhere to these instructions, any modifications to these procedures may alter the performance of the test.
• Negative result is not intended to rule in other non-SARS viral or bacterial infections.
• Negative result, from patient with symptom onset beyond seven days, should be treated as presumptive and confirmation with a molecular assay, if necessary, patient management may be performed.

• Positive test results do not differentiate between SARS-CoV and COVID-19.
• Positive test results do not rule out co-infections with other pathogens.
• False result may occur if specimen is tested after 1 hour of collection.
• False negative may occur if specimen is improperly collected, transported or handled.
• False negative may occur if specimen swab is not twirled within the test tube.
• If the differentiation of specific SARS virus and strain is needed, additional testing, in consultation with state local public health departments, is required.

## ATTENTIONS

1. The kit is only used for in vitro testing. Please read this instruction carefully before experiment and operate strictly in accordance with the instruction.
2. Reagents of different batch numbers cannot be mixed.
3. The collection, storage and testing of samples should be carried out in strict accordance with the "Technical Guidelines for Laboratory Testing of Pneumonia Infected by Novel Coronavirus (Second Edition)" and "Guidelines for Biosafety of Novel Coronavirus Laboratory (Second Edition)".
4. After the inspection, the remaining samples are preserved and various wastes are treated, and strictly abide by the "novel coronavirus Laboratory Biosafety Guidelines (Second Edition)" and the "Novel Coronavirus Pneumonia Clinical Laboratory Testing Biosafety Guidelines (Trial Section) First edition)" for treatment; the waste or remaining samples generated during the test process are recommended to refer to the above guidelines. First, use ether, 75% ethanol, chlorine disinfectant, peroxyacetic acid and chloroform and other lipid solvents to soak for virus inactivation. Then refer to the above guidelines to deal with infectious agents.
5. The test results of this kit are for clinical reference only, and the clinical diagnosis of the disease should be comprehensively considered in combination with its symptoms, signs, medical history, other laboratory tests and treatment response.

## CONSISTENCY ANALYSIS OF TEST RESULTS

### Consistency comparison of experimental reagent and reference reagent

In this study, 500 nasal and 500 saliva and 500 oropharynx swab samples were obtained in the clinical performance study to compare the results of the COVID-19 Antigen Sealing Tube Test Strip and the nucleic acid results. Analyzed the clinical performance data of the COVID-19 test results, and tested 200 samples that were positive for nucleic acid through the COVID-19 antigen sealing tube test strip, and 197 were positive. There were 300 negative samples for nucleic acid in the experimental reagents, and 297 negative samples were tested by the Reagent. Hence, the sensitivity and specificity were 98.5% and 99% respectively.

**Table 1 Overall Clinical Study Results for Nasal Swab**

| **Reagent test results** | **PCR Comparator** | |
|---|---|---|
| | positive | negative |
| **positive** | 197 | - |
| **negative** | 3 | - |
| **Subtotal** | 200 | - |
| **Reagent test results** | PCR Comparator | |
| | positive | negative |
| **positive** | - | 3 |
| **negative** | - | 297 |
| **Subtotal** | - | 300 |

Positive Percent Agreement (PPA）= 98.5%（95.3%~99.7%）
Negative Percent Agreement (NPA）= 99.0%（96.9%~99.7%）
Accuracy = 98.8%

**Table 2 Overall Clinical Study Results for Saliva Swab**

| **Reagent test results** | **PCR Comparator** | |
|---|---|---|
| | positive | negative |
| **positive** | 197 | - |
| **negative** | 3 | - |
| **Subtotal** | 200 | - |
| **Reagent test results** | PCR Comparator | |
| | positive | negative |
| **positive** | - | 3 |
| **negative** | - | 297 |
| **Subtotal** | - | 300 |

Positive Percent Agreement (PPA）= 98.5%（95.3%~99.7%）
Negative Percent Agreement (NPA）= 99.0%（96.9%~99.7%）
Accuracy = 98.8%

**Table 3 Overall Clinical Study Results for Oropharynx Swab**

| **Reagent test results** | **PCR Comparator** | |
|---|---|---|
| | positive | negative |
| **positive** | 197 | - |
| **negative** | 3 | - |
| **Subtotal** | 200 | - |
| **Reagent test results** | PCR Comparator | |
| | positive | negative |
| **positive** | - | 3 |
| **negative** | - | 297 |
| **Subtotal** | - | 300 |

Positive Percent Agreement (PPA）= 98.5%（95.3%~99.7%）
Negative Percent Agreement (NPA）= 99.0%（96.9%~99.7%）
Accuracy = 98.8%

## CROSS REACTIVITY (ANALYTICAL SPECIFICITY) STUDY:

### Amazingbio COVID-19 Antigen Sealing Tube Test Strip (Colloidal Gold) Cross Reactivity

The potential cross-reactivity of the Amazingbio COVID-19 antigen sealing tube test strip (Colloidal Gold) was evaluated by testing twenty-seven (27) commensal and pathogenic microorganisms (Wet testing: 16 viruses, 9 bacteria, 1 yeast, and 1 pooled human nasal wash) that may be present in the nasal cavity. Each organism, virus, bacteria, and yeast were tested in triplicate (3) in the absence or presence of 3x LoD of the heat-inactivated SARS-CoV-2 virus (NR-52287). No cross reactivity or interference was seen with the following microorganisms when tested at the concentration presented in the table below.

**Table 1 Amazingbio COVID-19 Antigen Sealing Tube Test Strip (Colloidal Gold) Cross Reactivity**

| **Virus/Bacteria/Parasite name** | **Strain** | **Wet-testing Concentration/ *In silico* testing** | **Cross Reactivity Results (Number of Positive/Total)** |
|---|---|---|---|
| Human coronavirus | 229E | 1.6 x $10^{5.0}$ TCID50/mL | No Cross-Reactivity (0/3) |
| Human coronavirus | OC43 | 1.6 x $10^{5.0}$ TCID50/mL | No Cross-Reactivity (0/3) |
| Human coronavirus | NL63 | 1.6 x $10^{3.0}$ TCID50/mL | No Cross-Reactivity (0/3) |
| MERS-coronavirus | EMC/2012 | 1.6 x $10^{5.0}$ TCID50/mL | No Cross-Reactivity (0/3) |
| Adenovirus | Serotype 5 | 1.6 x $10^{5.0}$ TCID50/mL | No Cross-Reactivity (0/3) |
| Human metapneumovirus (hMPV) | TN/91-320 | 1.6 x $10^{5.0}$ TCID50/mL | No Cross-Reactivity (0/3) |
| Human parainfluenza virus 1 | HPIV1/FRA/29221106/2009 | 8.9 x $10^{5.0}$ TCID50/mL | No Cross-Reactivity (0/3) |
| Human parainfluenza virus 2 | Greer | 1.0 x $10^{5.0}$ TCID50/mL | No Cross-Reactivity (0/3) |
| Human parainfluenza virus 3 | NIH 47885 | 1.6 x $10^{5.0}$ TCID50/mL | No Cross-Reactivity (0/3) |
| Human parainfluenza virus 4a | M-25 | 1.6 x $10^{3.0}$ TCID50/mL | No Cross-Reactivity (0/3) |
| Human parainfluenza virus 4b | 19503 | 5.0 x $10^{5.0}$ TCID50/mL | No Cross-Reactivity (0/3) |
| Influenza A | A/California/07/2009 | 5.2 x $10^{5.0}$ TCID50/mL | No Cross-Reactivity (0/3) |
| Influenza B | B/Hong Kong/330/2001 (Victoria Lineage) | 1.8 x $10^{5.0}$ TCID50/mL | No Cross-Reactivity (0/3) |
| Enterovirus | 71/Tainan/4643/98 | 1.6 x $10^{5.0}$ TCID50/mL | No Cross-Reactivity (0/3) |
| Respiratory Syncytial Virus A | 1998/12-21 | 2.8 x $10^{5.0}$ TCID50/mL | No Cross-Reactivity (0/3) |
| Rhinovirus | 16 | >5.0 x $10^{3.0}$ TCID50/mL | No Cross-Reactivity (0/3) |
| *Haemophilus influenzae* | Type B CK | >$10^{4.0}$ cfu/vial* | No Cross-Reactivity (0/3) |
| *Streptococcus pneumoniae* | Z022 | 3.6 x $10^{6.0}$ cfu/mL | No Cross-Reactivity (0/3) |
| *Streptococcus pyogenes* | Z018/M58 | 3.9 x $10^{6.0}$ org/mL | No Cross-Reactivity (0/3) |
| Pooled human nasal wash | N/A | N/A | No Cross-Reactivity (0/3) |
| *Bordetella pertussis* | 18323 [NCTC 10739] | 4.8 x $10^{6.0}$ cells/mL | No Cross-Reactivity (0/3) |
| *Mycoplasma pneumoniae* | M129 | 2.7 x $10^{6.0}$ cfu/mL | No Cross-Reactivity (0/3) |
| *Chlamydia pneumoniae* | TW-183 | 9.1 x $10^{6.0}$ IFU/mL | No Cross-Reactivity (0/3) |
| *Legionella pnuemophila* | Philadelphia | 1.9 x $10^{6.0}$ cfu/mL | No Cross-Reactivity (0/3) |
| *Staphylococcus aureus* | MRSA | 6.5 x $10^{5.0}$ cfu/mL | No Cross-Reactivity (0/3) |
| *Staphylococcus epidermidis* | MSSE;HER 1292 | 7.7 x $10^{6.0}$ cfu/mL | No Cross-Reactivity (0/3) |
| *Candida albicans* | Y537 | 5.0 x $10^{6.0}$ | No Cross-Reactivity (0/3) |

| | | | |
|---|---|---|---|
| | | cfu/mL | |

* No quantitation data provided. The stock concentration on the Certificate of Analysis (CoA) was >$10^4$ cfu/vial.

** IFU/mL is Infectious Units per milliliter.

**Table 2 Amazingbio COVID-19 Antigen Sealing Tube Test Strip (Colloidal Gold) organisms interference**

| Virus/Bacteria/Para site name | Strain | Wet-testing Concentration | Interference Results (Number of Positive/Total) |
|---|---|---|---|
| Human coronavirus | 229E | 1.6 x $10^{5.0}$ TCID50/mL | No Interference (3/3) |
| Human coronavirus | OC43 | 1.6 x $10^{5.0}$ TCID50/mL | No Interference (3/3) |
| Human coronavirus | NL63 | 1.6 x $10^{3.0}$ TCID50/mL | No Interference (3/3) |
| MERS-coronavirus | EMC/2012 | 1.6 x $10^{5.0}$ TCID50/mL | No Interference (3/3) |
| Adenovirus | Serotype 5 | 1.6 x $10^{5.0}$ TCID50/mL | No Interference (3/3) |
| Human metapneumovirus (hMPV) | TN/91-320 | 1.6 x $10^{5.0}$ TCID50/mL | No Interference (3/3) |
| Human parainfluenza virus 1 | HPIV1/FR A/29221106/2009 | 8.9 x $10^{5.0}$ TCID50/mL | No Interference (3/3) |
| Human parainfluenza virus 2 | Greer | 1.0 x $10^{5.0}$ TCID50/mL | No Interference (3/3) |
| Human parainfluenza virus 3 | NIH 47885 | 1.6 x $10^{5.0}$ TCID50/mL | No Interference (3/3) |
| Human parainfluenza virus 4a | M-25 | 1.6 x $10^{3.0}$ TCID50/mL | No Interference (3/3) |
| Human parainfluenza virus 4b | 19503 | 5.0 x $10^{5.0}$ TCID50/mL | No Interference (3/3) |
| Influenza A | A/California/07/2009 | 5.2 x $10^{5.0}$ TCID50/mL | No Interference (3/3) |

## ENDOGENOUS INTERFERENCE SUBSTANCES STUDIES:

Endogenous interference substances studies of the Amazingbio COVID-19 Antigen Sealing Tube Test Strip (Colloidal Gold) were evaluated by testing the following substances listed in the table below. Each substance was tested in triplicate (3) with 3x LoD, 2250 $TCID_{50}$/mL, inactivated SARS-CoV-2 virus (NR-52287). All samples tested produced expected results, demonstrating that the Amazingbio COVID-19 Antigen Sealing Tube Test Strip (Colloidal Gold) performance was not affected by any of the 14 potentially interfering substances listed in the table 3 below.

**Table 3 Endogenous interference study of Amazingbio COVID-19 Antigen Sealing Tube Test Strip (Colloidal Gold)**

| Potential Interfering Substances | Active Ingredient | Test concentration | Results (Number of Positive/Total) |
|---|---|---|---|
| Whole Blood | Blood (human) | 4 % V/V | No Interference (3/3) |
| Mucin | Mucin protein, Type I-S | 0.5 % W/V | No Interference (3/3) |
| Chloraseptic | Benzocaine, Menthol | 0.15 % W/V (1.5mg/ml) | No Interference (3/3) |
| Naso Gel (NeiMed) | Saline | 5.0 % V/V | No Interference (3/3) |
| Nasal Spray | Phenylephrine | 15.0 % V/V | No Interference (3/3) |
| Afrin | Oxymetazoline | 15.0 % V/V | No Interference (3/3) |
| Zicam | Oxymetazoline, Hydrochloride | 5.0 % V/V | No Interference (3/3) |
| Nasal Spray (Cromolyn) | Cromolyn sodium | 15.0 % V/V | No Interference (3/3) |
| Alkalol | Galphimia glauca, Luffa operculata, Sabadilla | 1:10 dilution | No Interference (3/3) |
| Sore Throat Phenol Spray | Phenol | 15.0 % V/V | No Interference (3/3) |
| Tobramycin | Tobramycin | 0.0004% W/V (4ug/ml) | No Interference (3/3) |
| Mupirocin | Mupirocin | 1.0 % W/V (10mg/ml) | No Interference (3/3) |
| Fluticasone Propionate | Fluticasone propionate (glucocorticoid) | 5.0 % V/V | No Interference (3/3) |
| Tamiflu | Oseltamivir | 0.5 % W/V (5 mg/mL) | No Interference (3/3) |

## HIGH-DOSE HOOK EFFECT:

The high-dose hook effect of the Amazingbio COVID-19 Antigen Sealing Tube Test Strip (Colloidal Gold) was evaluated by testing the following serial dilutions of the characterized SARS-CoV-2 listed in the table. No high dose hook effect was observed when tested with up to a concentration of 1.5 x $10^{5.0}$ or 1.0 x $10^{5.0}$ TCID50/mL of the inactivated SARS-CoV-2 virus (NR-52287) to the Hercin 2019-nCoV Antigen Test Kit.

Table 4 High-dose hook effect of Amazingbio COVID-19 Antigen Sealing Tube Test Strip (Colloidal Gold)

| SARS-CoV-2 Concentration (TCID50/mL) | High-dose Hook Effect Test Results (Number of Positive/Total) |
|---|---|
| 1.5×$10^{5.0}$ | Not Identified (3/3) |
| 1.0×$10^{5.0}$ | Not Identified (3/3) |

## 【INDEX OF SYMBOLS】

| | | | |
|---|---|---|---|
| IVD | For in vitro diagnostic use only. | | Do not reuse. |
| | Expiry date. | | See instruction for use. |
| | Warning, please refer to the instructions in the annex. | | Manufacturer. |
| 4℃ 30℃ | Temperature scope within which the product is reserved. | LOT | Batch number. |
| REF | Catalog # | | Tests per kit. |
| EC REP | European union authorized representative. | | Keep dry. |
| | Keep away from sunlight. | | Don't use the product when the package is damaged. |
| | Biological risks. | | Date of manufacture. |
| CE | The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC. | | |


**Manufacturer:**
**Amazing Biotech (Shanghai) Co.,LTD**
3/F, Building 1, No. 48-52 Gucui Road, Xinchang Town, Pudong New District, Shanghai, China.
E-mail: int_sales@amazingbio.cn Tel: 021-68071355

**European Authorized Representative:**
**Lotus NL B.V.**
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
E-mail: peter@lotusnl.com Tel: +31644168999



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