

COVID-19 (SARS-CoV-2) Antigen Test Kit Instruction for Use

[Product name]

COVID-19 (SARS-CoV-2) Antigen Test Kit

[Packing specification]

20 Tests/Kit

[Intended use]

This product is intended for in vitro qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in oropharyngeal (throat) swabs and nasopharyngeal swabs from individuals suspected of COVID-19 by their healthcare provider. The kit is intended for use by laboratory trained personnel.

Coronaviruses are a large family of viruses which could cause illness in animals or humans. The Novel Coronaviruses (SARS-CoV-2) belong to the RNA virus of the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough.

Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

[Test principle]

This kit employs immunochromatography for detection. The specimen will move forward along the test card under capillary action. If the SARS-CoV-2 viral antigen is present, they will be bound to the colloidal gold-labeled SARS-CoV-2 specific antibodies. The immune complex will be captured by coronavirus monoclonal antibody fixed in the T line. A fuchsia line would form, and the test result would be positive. If the line does not show color, the negative result will be displayed. The test card also contains a quality control line C, which shall appear fuchsia regardless of whether there is a detection line.

[Main components]

Components	Spec	20 tests/kit
Antigen Test cassette		20 pieces
Desiccant		20 pieces
Antigen extract R1		0.5mLx20 tubes
Instruction for use		1 piece
Oropharyngeal/Nasopharyngeal swab		20 pieces

Antigen extraction tube
(with tube and dropper head)

20 pieces

[Storage conditions & period of validity]

1. Store at 2°C~30°C, and it is valid for 24 months.
2. After the aluminum foil bag is unsealed, the test card should be used as soon as possible.

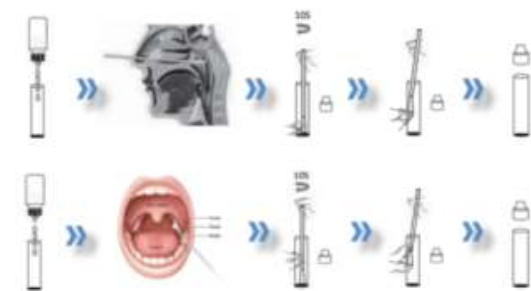
[Specimen request]

- **Oropharyngeal (throat) swabs:**
Let the patient's head tilt slightly, mouth open, and make "ah" sounds, exposing the pharyngeal tonsils on both sides. Hold the swab and wipe on both sides of the patient's pharyngeal tonsils, wipe it back and forth for at least 3 times and do it with moderate pressure applied; Place the swab specimen in the extraction tube with the Antigen extract R1 added in advance, rotate the swab for about 10 seconds, and press the swab head against the wall to release the antigen in the swab.
- **Nasopharyngeal swabs:**
Let the patient's head relax naturally, and slowly rotate the swab against the wall of the nostril into the patient's nostril to the nasal palate, and then slowly remove it while wiping. Using the same swab, wipe the other nostril in the same way; place the swab specimen in the extraction tube with the Antigen extract R1 added in advance, rotate the swab for about 10 seconds, and then squeeze the swab head from the tube wall to release the antigen in the swab.

[Test methods]

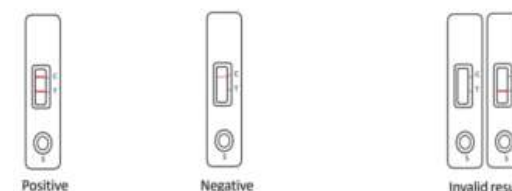
1. Unseal the package and take out the antigen test cassette.
2. Place the extraction tube on the workbench. Place the Antigen extract R1 bottle vertically downward to allow the solution to drip freely into the extraction tube without touching the edge of the tube. Add 6 drops of R1 to the extraction tube.
3. Put the swab specimen into the extraction tube, rotate the swab for about 10 seconds, and press the swab head against the tube wall to release the antigen in the swab. Squeeze the swab over the head while taking the swab out of the extraction tube to remove as much liquid as possible from the swab. Dispose of swabs according to biohazard waste disposal method.
4. Install the dropper head on the extraction tube, put two drops into the specimen well of the test cassette, and start the timer.
5. Read the results within 15 minutes. Strong positive results can be reported within 15 minutes, however, negative results must be reported after 15 minutes, and the results after 25 minutes are no longer valid.

IVD



[Interpretation of test results]

- **Positive result:** if both the quality control line C and the detection line appear, novel coronavirus antigen has been detected and the result is positive for antigen.
- **Negative result:** if there is only a quality control line C, the detection line is colorless, indicating that novel coronavirus antigen has not been detected and the result is negative.
- **Invalid result:** if the quality control line C is not observed, it will be invalid regardless of whether there is detection line (as shown in the figure below), and the test shall be repeated.



[Limitations of inspection methods]

1. This reagent is only used for in vitro diagnosis.
2. This reagent is only used to detect human Sterile swab extracts. The results of other specimens may be inaccurate.
3. This reagent is only used for qualitative detection and cannot indicate the level of novel coronavirus antigen in the specimen.
4. This reagent is only a clinical auxiliary diagnostic tool. If the result is positive, it is recommended to use other methods for further examination in time and the doctor's diagnosis shall prevail.

[Product Performance Indicators]

1. LoD: The LoD for direct swab was established using heat-inactivated SARS-CoV-2. The strain was spiked into the pooled human oropharyngeal swab matrix obtained from multiple healthy volunteers eluted in R1 and confirmed as SARS-CoV-2 negative by RT-PCR to prepare positive samples. The estimated LoD found from the initial serial dilution test was confirmed by testing 20 replicates. The confirmed LoD for direct swab was 5×10^2 TCID₅₀/ml.

2. Negative Agreement: Test the negative reference, and the negative accordance rate shall be 100%.

3. Positive Agreement: Test the positive reference, and the positive accordance rate shall be 100%.

4. Precision: Test the precision references, the test results shall be positive with uniform color.

5. Analytical Specificity

1) Cross-reactivity: No false positive test results for either COVID-19 (SARS-CoV-2) Antigen Test Kit were observed on specimens from the following disease states or specific conditions:

Staphylococcus aureus, streptococcus pneumonia, measles, mumps virus, Adenovirus (type 3, C1, 71), Mycoplasma pneumonia, parainfluenza virus (1-4) (2), Mycobacterium tuberculosis, Coronavirus OC43, 229E, NL63, HKU1, bordetella pertussis, Influenza B Virus (Victoria), Influenza B Virus (Yamagata), H1N1, H3N2, EBV, Coxsackievirus A16 (CVA16), Rhinovirus, Respiratory syncytial virus, Chlamydia pneumoniae, Haemophilus influenzae, Legionella pneumophila, Mycobacterium tuberculosis, Streptococcus pyogenes, Pneumocystis jirovecii (PJP), Pooled human nasal wash.

2) Interference: No interference was observed with the potentially interfering substances listed below at the indicated concentration:
Commonly used drugs, i.e., Phenylephrine, Oxymetazoline, sodium chloride, beclomethasone, dexamethasone, flunisolide, triamcinolone acetonide, budesonide, mometasone, fluticasone, Histamine hydrochloride, alpha-interferon, zanamivir, ribavirin, oseltamivir, peramivir, Lopinavir, Ritonavir, Arbidol, levofloxacin, azithromycin, ceftriaxone, meropenem, tobramycin, mucin, blood (human), Human Anti-mouse Antibody (HAMA), biotin have no effect on the test results of this kit.

6. Clinical Performance

Contrast Results Statistics of Clinically Confirmed/Excluded Results (267 oropharyngeal swabs + 267 nasopharyngeal swabs)

Evaluation Reagent	Clinical Confirmed/Excluded Results		Total
	Confirmed	Excluded	
Positive	125	3	128
Negative	5	401	406
Total	130	404	534

Result calculation:

(1) Clinical sensitivity: 96.15%, 95% confidence interval: [91.31%, 98.35%].

(2) Clinical specificity: 99.26%, 95% confidence interval: [97.84%, 99.75%].

(3) Clinical accuracy: 98.50%, 95% confidence interval: [97.07%, 99.24%].

*In the stratified statistics of different stages of the disease, 52 specimens from 0-3 days, and the positive detection rate is 98.08%.

[Precautions]

1. This reagent must be used by trained or professional clinical testing personnel by following all laboratory management regulations.

2. Read the instructions carefully before using the kit, and strictly control the reaction time. If you do not follow the instructions, you will get inaccurate results.

3. The specimen shall be tested in a laboratory with certain conditions. All specimens and materials during testing should be handled in accordance with the laboratory practice for infectious diseases.

4. Protect from moisture, do not open the aluminum platinum bag before it is ready for testing. Do not use when the aluminum foil bag is damaged or the test card is damp.

5. Please use it within the validity period.

6. Wait all reagents and specimens come to room temperature (15 ~ 30 °C) before use.

7. Do not replace the components in this kit with components in other kits.

8. Do not dilute the specimen for testing, otherwise you may get inaccurate results.

9. The kit shall be stored in strict accordance with the conditions specified in this manual. Please do not store the kit under freezing conditions.

10. The test methods and results must be interpreted in strict accordance with this specification.

[Index of Symbols]

	Temperature Limit		Use-by date
	Batch/Lot code		In vitro diagnostic medical device

IVD

CE

	Manufacturer		Catalogue number
	Contains sufficient for <N> tests		Consult instructions for use
	Do not re-use		
	Date of manufacture		Authorized representative in the European Community
	Do not use if package is damaged		Sterilized using irradiation
	CE Certification		

[INFORMATIONENINQUIRIES AND GENERAL INFORMATION]



Wuhan EasyDiagnosis Biomedicine Co., Ltd.

Address: Room 3 & 4, 2nd Floor, Bldg 25, Phase 3.1 Wuhan Optics Valley International Biopharmaceutical Enterprise Accelerator, No.388, Gaoxin 2nd RD, East Lake Hi-Tech Development Zone, 430074 Wuhan, China

Tel: +86(0)27-87808955

Fax: +86(0)27-87808005

Web: www.mdeasydiagnosis.com

Email: info@ediagnosis.cn



MedNet EC-REP GmbH

Borkstrasse 10, 48163 Münster, Deutschland

[SWAB INFORMATION]



Shenzhen KangDaAn Biological Technology co., Ltd.

East- 1, 3rd floor, Building 2, Shunheda factory, Liuxiangdong industrial zone, Xili street, Nanshan district, Shenzhen .

Tel: +86 0755- 82836262

Fax: +86 0755- 83426595

Web: www.kdasw.com



Name: Share Info Consultant Service LLC Repräsentanzbüro
Address: Heerdter Lohweg 83, 40549 Düsseldorf