Vazyme

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Detection Kit

(Colloidal Gold-Based)

Rapid & Portable kit for Large-Scale Screening

Vazyme Online

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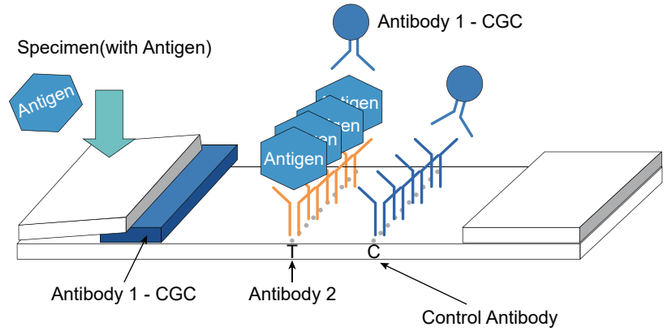
Intended Use

SARS-CoV-2 Antigen tests are immunoassays that use highly sensitive monoclonal antibodies to detect the presence of virus. With saliva specimens directly into the assay's extraction buffer or reagent, antigen tests can be used for screening in high-risk congregate settings in which repeat testing could quickly identify SARS-CoV-2-infected individuals for infection prevention and control, thus preventing transmission.

Product Advantages

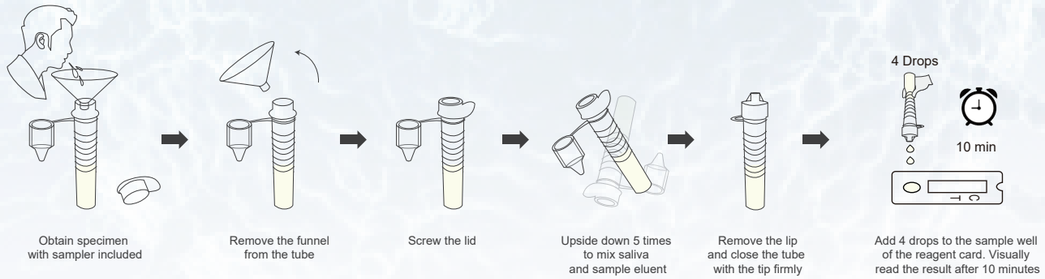
- Highly portable
- Prepacked eluent buffer, ready to use
- Easy to operate, no instrument needed
- Good consistency with PCR test
- Time saving (10 min)
- Room-temperature storage (4-30 ˚C)

Principle



The double antibody sandwich method is adopted for this product to implement determination in the form of solid phase immunochromatography.

Operation Flow



Obtain specimen with sampler included

Remove the funnel from the tube

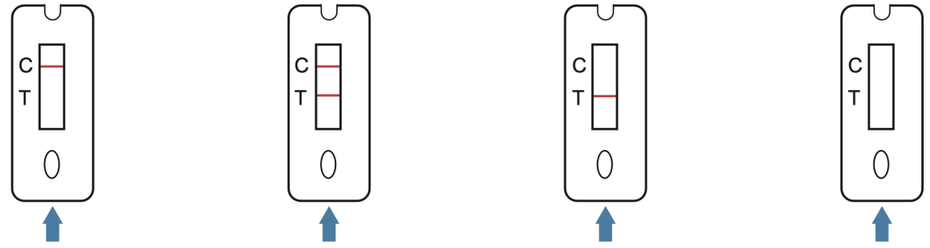
Screw the lid

Upside down 5 times to mix saliva and sample eluent

Remove the lip and close the tube with the tip firmly

Add 4 drops to the sample well of the reagent card. Visually read the result after 10 minutes

Interpretation of Test Results



Negative

Positive

Invalid

Invalid

Performance

		Result of Clinical Diagnosis		Total
		Positive(+)	Negative(-)	
Kit test result	Positive	87	0	87
	Negative	1	112	113
Total		88	112	200

Sensitivity: 97.57% [95%CI: 94.45%, 98.60%]

Specificity: 99.29% [95%CI: 98.54%, 99.66%]

Total agreement: 98.99% [95%CI: 98.25%, 99.42%]

LOD: 50 $TCID_{50}$ /mL

Kit contents

Funnel

Collection tube

Test cassette

Order information

5 Tests/Kit

20 Tests/Kit

Cat. No	Specimen	Packing Size	Shelf Life	Storage
C8610CT	Saliva	5 Tests/Kit	18 Months	4℃–30℃
C8602CT	Saliva	20 Tests/Kit	18 Months	4℃–30℃

Contact Info:
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8. Hook effect: There is no hook effect when the SARS-CoV-2 positive specimen with concentration up to 1.92×10^5TCID$_{50}$/mL is tested at the original concentration.
9. Limit of Detection (LOD): The LOD of the product is determined after gradient dilution is carried out for the SARS-CoV-2 positive specimen using the solution after eluting the negative sample of a normal person as negative matrix diluent. The LOD of the product is 50 TCID$_{50}$/mL SARS-CoV-2.

[PRECAUTIONS]

1. This product is only for in vitro diagnosis.
2. Only the tester who has received professional training can perform test operations strictly according to the instructions for the kit after reading through the instructions carefully.
3. Wear protective clothing such as medical protective clothing, protective gloves and goggles when collecting and evaluating specimens.
4. Dispose of all the components as biohazardous waste in accordance with national regulations and procedures upon completion of each test.

[Basic Information]

Manufacturer: Nanjing Vazyme Medical Technology Co., Ltd.
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EC REP

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[APPROVAL DATE& MODIFICATION DATE OF INSTRUCTION FOR USE]

February 14, 2021

[Symbols]

EC REP	Authorized Representative In the European Community
IVD	For in vitro diagnostic use only
4°C 30°C	Stored at 4 ~ 30°C
	Production Date
Σ	Tests per kit

REF	Catalog #
LOT	Batch Code
	Do not reuse
	Do not use if package damaged

	Manufacturer
	Expire Date
	Consult instructions for use
CE	CE Mark

Nanjing Vazyme Medical Technology Co., LTD.
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IVD CE

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Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Detection Kit (Colloidal Gold-Based) （Version 7.2）

[NAME]

Generic Name: Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Detection Kit (Colloidal Gold-Based)

[SPECIFICATION]

20 tests/kit; 50 tests/kit

[INTENDED USE]

This kit is applicable to clinical qualitative detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antigen in human saliva samples in vitro.
For in vitro diagnostic use only, for professional use only.

[PRINCIPLE OF INSPECTION]

The double antibody sandwich method is adopted for this product to implement determination in the form of solid phase immunochromatography. The sample to be tested diffuses upward by capillary force at the sampling end, and when passing by the marker pad, the SARS-CoV-2 antigen in the sample is combined with the antibody on the marker pad to form a colloidal gold antibody-antigen complex. The complex continues to spread with the sample to reach the nitrocellulose membrane and is intercepted by the T-line (test line) coated with antibody, and the complex is captured to form an immune complex of colloidal gold antibody conjugates-antigen-coating antibody. The remaining colloidal gold conjugates continue to ascend and are combined with C-line (quality control line), indicating completion of the reaction.

[MAIN COMPONENTS]

REF / Component name	C8602CT	C8605CT	C8602CD	C8605CD
Detection card (pcs)	20	50	20	50
Sample eluent	20	50	20	50
Sampler (pcs)	20	50	/	/
Paper pouch	/	/	20	50
Dropper	/	/	20	50

Note: The components of different batches are not interchangeable.
Materials Required but not provided:
• Timer
• Personal protective equipment, such a protective gloves, medical mask, goggles and lab coat.
• Appropriate biohazard waste container and disinfectants.

[STORAGE CONDITION AND VALIDITY PERIOD]

The kit is stored in a sealed state at 4°C to 30°C away from light for a validity period of 18 months. Once the package of the Test Cassette is opened (4°C~30°C, humidity <65%), it must be used within 1 hour.
Production date and expiration date: See the label.

[SPECIMEN COLLECTION AND PREPARATION]

PROCEDURE I (For C8602CT, C8605CT)
Rinse the mouth with clear water 30 minutes before collection, place the tip of the tongue against the root of the maxillary or mandibular teeth to enrich saliva, gently spit saliva into the elliptical funnel, hold the funnel in one hand and stand upright, hold the saliva collection tube in the other, spit two mouthfuls. Seal the collection tube and upside down 5 times to mix saliva and sample eluent. Check that the sample collection tube is in good condition, cracks, cover leakage and sample overflow, then discard the used funnel.
PROCEDURE II (For C8602CD, C8605CD)
Rinse the mouth with clear water 30 minutes before collection, place the tip of the tongue against the root of the maxillary or mandibular teeth to enrich saliva, open a paper pouch and directly spit saliva into it. Use a dropper to draw saliva from a paper bag and drop it into a sample eluent, Cover the lid and shake to mix the specimen completely. Check that the sample collection tube is in good condition, cracks, cover leakage and sample overflow.

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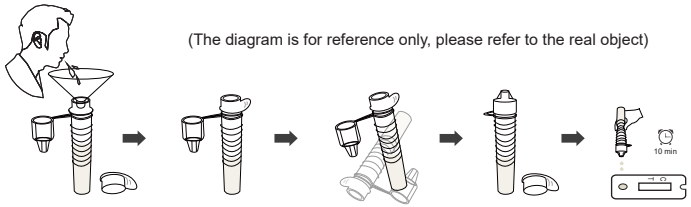
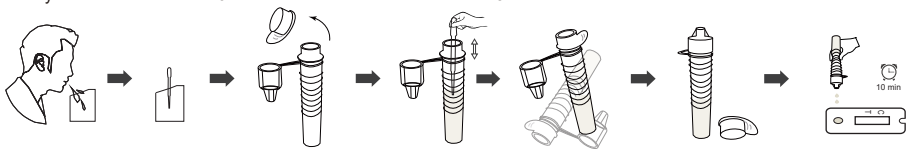
[TEST PROCEDURE]

PROCEDURE I (For C8602CT, C8605CT)
1.Rinse the mouth with clear water 30 minutes before collection, gently spit saliva into the elliptical funnel, hold the funnel in one hand and stand upright, hold the saliva collection tube in the other, spit two mouthfuls.
2.Remove the funnel and close the lid.
3.Upside down 5 times to mix saliva and sample eluent.
4.Remove the lip and close the tube with the tip firmly.
5.Turn upside down and squeeze the tube to add 4 drops (about 80 μL) to the sample well of the reagent card, and start counting.
6.Visually read the result after 10 minutes. The result is invalid after 15 minutes.



(The diagram is for reference only, please refer to the real object)

PROCEDURE Ⅱ (For C8602CD, C8605CD)
1.Open the paper pouch and directly spit saliva into it.
2.Use a disposable dropper to absorb the saliva specimen
3.Open the lid of the elution tube, squeeze the dropper, and slowly drop saliva into the eluent.
4.Close the lid and upside down 5 times to mix saliva and sample eluent.
5.Remove the lip and close the tube with the tip firmly.
6.Turn upside down and squeeze the tube to add 4 drops (about 80 μL) to the sample well of the reagent card, and start counting.
7.Visually read the result after 10 minutes. The result is invalid after 15 minutes.



(The diagram is for reference only, please refer to the real object)

[SPECIMEN REQUIREMENTS]

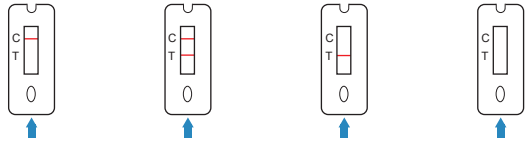
1. The applicable specimen type of this detection card is saliva samples.
2. The specimens should be eluted with the sample eluent provided with this kit immediately after collection, and tested as soon as possible after elution. If the specimens cannot be processed immediately, preserve them as follows: one day at 2°C-8°C and permanently at -70°C and below.
3. Before test, the specimens must be fully restored to the room temperature. The frozen specimens should be fully thawed, rewarmed and mixed before use. Remember not to freeze and thaw them repeatedly.

[INSPECTION METHOD]

Please read the Instructions carefully before operation.
1. Recover the test strip and specimen eluent fully to the room temperature before use.
2. Take out the detection card from the aluminum foil bag and place it on a horizontal and dry plane.
3. After the specimen is collected,extract it up and down for at least 10 times (or at least 15 seconds), put on the upper cover of the elution tube, put it upside down on the sampling hole of the reagent card, gently squeeze the elution tube, and drip 4 drops (about 80 μL) into the sampling hole of the reagent card, and start timing.
5. Be sure to observe the detection card in 10 minutes after the test starts and judge the result. The results observed after 15 min are invalid.

[EXPLANATION OF INSPECTION RESULT]

1. Due to factors such as differences in methodology or antibody specificity, deviations may exist between the test results of reagents provided by respective manufacturers. Therefore, the test results cannot be compared directly, lest wrong medical interpretation would be caused.
2. The test results are determined as follows:



(This picture is for reference only, and the real product should prevail.)

1) Negative result: Only one red quality control line (C-line) is visible.
2) Positive result: Two clear red lines are visible, one is quality control line (C-line), and the other is the T test line.
3) Invalid result: There is no red line or there is only T test line, but no quality control line (C-line), suggesting that the item has a test error or the test result is invalid, and the item should be retested.

[LIMITATIONS OF INSPECTION METHOD]

1. The test results of the product are for clinical reference only, and should not be used as the only basis for clinical diagnosis and treatment. The clinical management of patients should be considered in conjunction with their symptoms/signs, medical history, other laboratory tests, treatment reactions, epidemiology and other information. Retest is recommended after a period of time for the suspicious specimens.
2. The test accuracy is affected by the specimen collection process, and improper specimen collection and storage process will affect the test results. High temperature and direct sunlight must be avoided.
3. This reagent can be used to carry out qualitative detection only for the SARS-CoV-2 antigen in specimens.
4. The negative result cannot exclude the possibility of SARS-CoV-2 infection due to the limitation of antigen detection reagent methodology, and the antigen in the specimen may be below the detection limit. Therefore, other detection results and comprehensive clinical judgment must be combined to make an accurate diagnosis.
5. The kit can detect the SARS-CoV-2 antigen in the specimen and whether the virus in the specimen is inactivated. It has no correlation with the cell culture results of the same specimen.
6. If SARS-CoV-2 antigen is positive, the result cannot rule out the presence of other co-infection pathogens.
7. The minor changes of SARS-CoV-2 in amino acids in the target region may result in the failure of monoclonal antibody detection or the decrease of detection sensitivity.
8. When collecting samples, use the sample collector provided by this kit and the corresponding collection method.
9. Proper specimen collection, storage and transportation are critical to the performance of the test.

[PERFORMANCE INDICATORS]

1. Limit of Detection reference: S1~S4: SARS-CoV-2 detection results are positive; S5~S6: not required.
2. Coincidence rate of positive reference: PC1~PC8: SARS-CoV-2 detection results are all positive.
3. Coincidence rate of negative reference: NC1~NC20: SARS-CoV-2 detection results are all negative.
4. Repeatability: CV1~CV2: SARS-CoV-2 detection results are all positive with consistent color rendering.
5. Inter-batch precision: The repeatability test is performed for three batches of kits, and the test results of three batches of kits meet the repeatability requirements.
6. Cross reaction: The product is verified by pathogenic microorganisms with a variety of common cross reactions which easily cause the same and similar symptoms clinically, and the results show no cross reaction.

Human coronavirus 229E	Measles virus	Mycoplasma pneumoniae	Staphylococcus aureus
Human coronavirus OC43	Mumps virus	Chlamydia pneumoniae	Streptococcus pneumoniae
Human coronavirus NL63	Adenovirus	Influenza A virus	Candida albicans
Human coronavirus HKU1	Parainfluenza virus 1-4	Influenza B virus	Mycobacterium tuberculosis
MERS coronavirus	Human metapneumovirus	Respiratory syncytial virus	Bordetella pertussis
EB virus	Avian influenza virus	Rhinovirus	Legionella pneumophila
Enterovirus	Haemophilus influenzae	Streptococcus pyogenes	-

7. Interference response: Interference verification is carried out for the product according to the maximum plasma concentration of common clinical therapeutic drugs in the following table under normal usage and dosages, and the results indicate that the product showcases good anti-interference performance.

Interfering substance	Concentration	Interfering substance	Concentration
Mucin	10 mg/mL	Meropenem	1 μg/mL
Ribavirin	2.0 mg/mL	Peramivir	20 μg/mL
Oseltamivir	375 μg/mL	Ceftriaxone	100 mg/mL
Azithromycin	0.15 g/L	Beclomethasone	200 μg/L
Tobramycin	0.125 mg/mL	Budesonide	0.64 nmol/L
Levofloxacin	5 μg/mL	Oxymetazoline	500 μg/mL
α-interferon	3,000,000 U	Mucus	-
Sodium chloride	0.9%	Whole blood	-
Human Anti-mouse Antibody (HAMA)	-		