[Address] Floor 1-3, Building C2, Red Maple Park of Technological Industry, Kechuang Road, Economy & Technology Development Zone, Nanjing, China
[Tel] +86 25 8436 5701 [Website] www.vazymemedical.com

10. Clinical performance: This study enrolled a total of 1194 specimens, the test results are as follows:

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-COV-2) Antigen Detection Kit (Colloidal Gold-Based)	PCR Comparator		Subtotal
	Positive	Negative	
Positive	201	7	208
Negative	5	981	986
Subtotal	206	988	1194
Sensitivity	97.57% (95% CI: 94.45% to 98.96%)		
Specificity	99.29% (95% CI: 98.54% to 99.66%)		
Accuracy	98.99% (95% CI: 98.25% to 99.42%)		

[PRECAUTIONS]

1. This product is 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.
Address: Floor 1-3, Building C2, Red Maple Park of Technological Industry, Kechuang Road, Economy & Technology Development Zone, Nanjing, China.
Tel: +86 25 8436 5701
E-mail: support@vazyme.com
Website: www.vazymemedical.com

EC REP

Obelis s.a.
Bd Général Wahis 53 1030 Brussels, Belgium
Tel:+(32)2732-59-54
Fax:+(32)2732-60-03
E-mail: mail@obelis.net

* Disposable swabs included in this kit have been individually CE marked by a third manufacturer. Please see below details and CE mark applied by said third manufacturer.
Name and Registered address of third manufacturer:
Jiangsu Changfeng Medical Industry Co., Ltd.
Touqiao Town, Guangling District, Yangzhou, Jiangsu 225109 China
European Authorized representative of the third manufacturer:
Landlink Gmbh Dorfstrasse 2/4, Emmendingen
CE mark applied on Disposable swabs by third manufacturer:

CE 0197

[APPROVAL AND REVISION DATE OF THE INSTRUCTIONS]

March 26, 2021

[Symbols]

EC REP	Authorized representative in the European Community
IVD	*In vitro* diagnostic medical device
4°C 30°C	Temperature limit 4 ~ 30°C
	Date of manufacture
Σ	Contains sufficient for <*n*> tests

REF	Catalogue number
LOT	Batch Code
	Do not re-use
	Do not use if package damaged

	Manufacturer
	Use-by date
	Consult instructions for use
CE	CE Mark

Nanjing Vazyme Medical Technology Co., LTD.
Floor 1-3, Building C2, Red Maple Park of Technological Industry, Kechuang Road, Economy & Technology Development Zone, Nanjing, China
www.vazymemedical.com

IVD CE

EC REP
Obelis s.a.
Bd Général Wahis 53
1030 Brussels, Belgium

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Detection Kit (Colloidal Gold-Based)（Version 8.1）

[NAME]

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

[SPECIFICATION]

1 test/kit; 5 tests/kit; 20 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 nasal swab, nasopharyngeal swab and oropharyngeal swab samples in vitro.
For in vitro diagnostic use , for professional use .

[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]

Component name	Main composition
Test Cassette	Aluminum foil bag, desiccant, test strip, and plastic card. The test strip is composed of absorbent paper, nitrocellulose membrane, cushion pad, sample pad, colloidal gold marker pad, and PVC board. The T-line (test line) of nitrocellulose membrane is coated with about 1.0 mg/mL mouse anti-SARS-CoV-2 monoclonal antibody, the C-line (quality control line) is coated with about 1.0 mg/mL internal reference protein C, and the marker pad contains about 40 OD mouse anti-SARS-CoV-2 antibody colloidal gold conjugates.
Sample eluent	Surfactant-containing phosphate buffer 0.5 mL/tube (0.01M, pH 7.4±0.2)
Disposable swab	It is used for sample collection and transfer.

Note: The components of different batches are not interchangeable.
Materials Required but not provided:
• timer
• tube rack for specimens

[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（C8611CA, C8610CA, C8602CA）
Nasal swab: Make sure the nasal cavity is moist. The tip of the swab should be inserted between 3 and 4 cm until resistance is felt. Roll the swab along the inner wall of the nostril 5 times to ensure that mucus and cells are collected. Using the same swab, repeat this process for the other nostril to ensure that a feasible sample is taken from both nostrils. Remove the swab from the nasal cavity.
PROCEDURE Ⅱ（C8611C, C8610C, C8602C）
Nasolpharyngeal swab: A sampling operator gently lifts the head of the person from whom specimens are collected with one hand and holds the swab in the other hand, with the swab entering through the nostrils and slowly going deep backwards along the bottom of the inferior meatus. Excessive force should be avoided in case of traumatic hemorrhage due to arc-shape of the nasal meatus. When the tip of the swab reached the posterior wall of the pharyngonasal cavity, rotate it gently for one revolution (stop for a minute in the case of a reflex cough) and then slowly remove the swab and transfer it to an elution tube.
PROCEDURE Ⅲ（C8611CY, C8610CY, C8602CY）
Oropharyngeal swab: The person from whom specimens are collected should first rinse the mouth with normal saline, and the sampling operator moistens the swab in sterile normal saline (the swab is forbidden to be put in virus preservation solution in case of allergy caused by antibiotics); and the person from whom specimens are collected lifts head slightly, with mouse opened, accompanied by an "Ah" sound, to expose the bilateral pharyngeal tonsils. Make the swab pass over the tongue root, wipe it back and forth with slight force on the bilateral pharyngeal tonsils of the person from whom specimens are collected for at least 3 times, and up and down on the posterior pharyngeal wall for at least 3 times, then transfer it to an elution tube.

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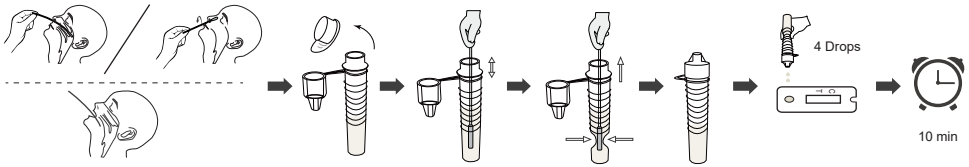
[TEST PROCEDURE]

1. Sample collection: Collect nasal swabs, nasopharyngeal swabs and oropharyngeal swabs according to the method of sample collection.
2.Remove the white cap from extraction reagent tube.
3. Insert the sample swab into the tube (immerse the sample part in the elution buffer), make sure the sample is removed into the buffer by rubbing and stirring the sampled swab up & down for 10 times.
4. Squeeze the tube and the swab to leave the eluent on the swab completely in the elution tube.
5. Mix the sample by gently turning the tube upside down, 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.



[SPECIMEN REQUIREMENTS]

1. The applicable specimen type of this detection card is nasal swab, nasopharyngeal swab and oropharyngeal swab.
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.

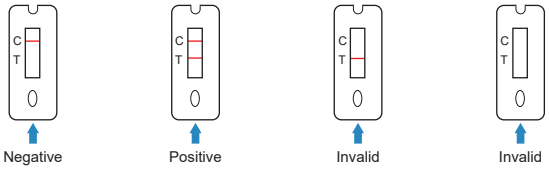
[INSPECTION METHOD]

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, add it into 0.5 mL of specimen eluent, extract it up and down for at least 10 times (or at least 15 seconds), and finally squeeze the swab, removing the eluent completely from the swab and leaving it in the eluent tube and mixing the elute well.
4. 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. Please use the swab provided in the kit when collecting swab specimens.
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)	-		

8. Hook effect: There is no hook effect when the SARS-CoV-2 positive specimen with concentration up to $1.92\times10^5 TCID_{50}$/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 nasal swab of a normal person as negative matrix diluent. The LOD of the product is 50 $TCID_{50}$/mL SARS-CoV-2.