[PRECAUTIONS]

1.Inspectors shall receive professional training and read the specification carefully before operation, and operate the test in strict accordance with the specification of the kit.
2.Leave test Cassette sealed in its foil pouch until just before use. Do not use if pouch is damaged or open.
3.Do not use kit past its expiration date.
4.Do not mix components from different kit lots.
5. Do not reuse the used test card.
6.Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when specimens are collected and evaluated.
7.For each test, please treat all components of this kit as biohazardous waste and dispose of these as per site, local, regional and national regulations and procedures.

[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) 2 732-59-54
Fax: +(32) 2 732-60-03
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 DATE& MODIFICATION DATE OF INSTRUCTION FOR USE]

October 22, 2020

[Symbols]

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

[PRODUCT NAME]

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

[SPECIFICATION]

20 tests/kit

[INTENDED USE]

The test kit is applicable to detect the antigen of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen in human throat swab, Nasal swab samples.

[PRINCIPLE OF DETECTION]

The double antibody sandwich method is adopted in the product, and measurement is conducted in the form of solid-phase immune chromatography. The sample to be tested will diffuse upwards at the charging end under capillary action, and then SARS-CoV-2 antigen in the sample will combine with the antibody in the marker pad and form colloidal gold antibody-antigen complex; The complex continues to diffuse to the nitrocellulose membrane with the sample, and then blocked by T-line (test line) packed with antibody, and form colloidal gold labeled antibody-antigen-immune complex packed with antibody. The rest unblocked colloidal gold complex continues to move upwards, and combine with C-line (quality control line), indicating that the reaction is completed.

[COMPONENTS PROVIDED IN THIS KIT]

Components	Description
Test Cassette-20	Aluminum foil bag, desiccant, test strip, and plastic card. The test strip consists of absorbent paper, nitrocellulose membrane, sample pad, colloidal gold marker pad, and polyvinyl chloride pane. Nitrocellulose membrane T-line (test line) is packed with about 1.0mg/mL SARS-CoV-2 monoclonal antibody, while C-line (quality control line) is packed with about 1.0mg/mL internal reference protein C, and the marker pad contains about 40 OD anti-mouse SARS-CoV-2 antibody colloidal gold complex.
Sample eluent-20	phosphate buffer with surfactant 0.5 ml/piece (0.01M, pH7.4±0.2).
Disposable swabs*-20	For sample collection and transfer.

Note: DO NOT interchange the components from different batches.

Materials Required but not provided:

• timer

• tube rack for specimens

• any necessary personal protective equipment

[STORAGE CONDITIONS & SHELF LIFE]

The shelf life of this kit is18 months at 4°C~30°C.
Once the package of the Test Cassette is opened (4°C~30°C, humidity <65%), it must be used within 1 hour.

Digitally signed by Iurchevici Valeriu
Date: 2020.11.25 19:01:25 EET
Reason: MoldSign Signature
Location: Moldova

[SPECIMEU REQUIREMENTS]

1. Applicable sample types of the test card include throat swab, Nasal swab.
2. Sampling:

1) Nasal Swab: The sampling personnel shall hold the head of the sampled personnel gently with one hand, and the swab with the other hand, put it inside the nostril, and go deep along nose bottom. Given the arced nasal passage, be cautious to act gently, and avoid traumatic bleeding. As the swab top reaches to the rear wall of the pharyngonasal cavity, rotate for a cycle gently (in case of reflective cough, stay for a minute), and then take it out slowly, and put it inside the elution tube.

2) Throat Swab: The sampled personnel shall rinse the mouth with saline solution at first, and then the sampling personnel shall put the swab into sterile saline solution (prevent from putting the swab into the virus preserving fluid, and avoid antibiotics from causing allergies), hold the sampled personnel's head up slightly, with their mouth open wide, and give out the sound of "Ah", expose the pharyngeal tonsils at two sides, and then use the swab to pass the root of tongue, and swipe the pharyngeal tonsils at the two sides of the sampled personnel for at least 3 times, and then swipe the rear wall of the throat upwards and downwards for at least 3 times, and then put the swab into the elution tube.

3. Samples shall be eluted in 1h, and tested as soon as possible afterwards. In case of failing to process immediately, please store under the following conditions: It can be stored for 1 day under 2°C-8°C, and for a long term under -70°C and below.
4. Samples shall be fully recovered to the room temperature before test. Cryo-preserved samples can only be used after being fully melted, re-warmed and evenly mixed, and prevent from repeated freezing and thawing.

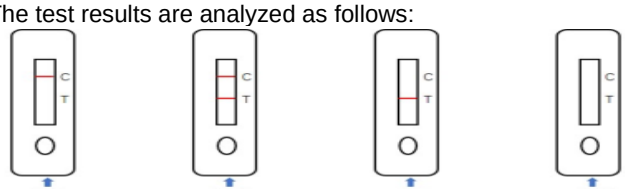
[TEST METHODS]

Read the instructions for use carefully before use.

1. The test cassette must be at room temperature before use, and the test must be operated at room temperature.
2. Remove the test cassette from the foil pouch and place on a flat, dry table.
3. After specimen collection, add the portion of swab where sample was collected to 0.5mL sample eluent for even elution.
4. Cover the upper cover of the elution tube and place it upside down above the sample hole of the reagent card, gently squeeze the elution tube, add 4 drops (about 80μL) to the charging hole of the reagent card, and start counting.
5. Read the results after 10 minutes. The result is invalid after 15 minutes.

[INTERPRETING TEST RESULTS]

The test results are analyzed as follows:



1. Negative result: Only one red quality control line (C-line) is visible.

2. Positive result: Two clear red lines are visible, one is the quality control line (C-line), while the other is the T test line.
3. Invalid result: No red lines are visible or only the test line is visible, without the quality control line (C-line), indicating that the test of the item is wrong or the test result is invalid, and retest is required.

[LIMITATIONS OF TEST METHODS]

1. The test result of the product is for clinical reference only, and shall not be used as the only basis for clinical diagnosis. Clinical management of patients shall be combined with the symptoms/physical signs, medical history, other laboratory tests, therapeutic response, epidemiology, etc., and suspicious samples shall be retested after certain periods.
2. Test accuracy can be influenced by the sampling process, and improper sampling and storage will influence the test result. It's requested to avoid high temperature and direct sunlight.
3. The reagent only provides qualitative test of SARS-CoV-2 antigen in the sample, and quantitative test is impossible.
4. Due to restrictions of antigen test reagent methodology, negative result cannot eliminate the possibility of being infected with SARS-CoV-2, for antigen in the sample may be lower than the test limit, and shall be judged in combination with other test results and clinical considerations, to provide accurate diagnosis.
5. The kit is used to test SARS-CoV-2 antigen in the sample, and whether the virus in the sample is invalid, with no relation to the cell cultivation result of the same sample.
6. SARS-CoV-2 positive antigen cannot eliminate other infectious agents.
7. Tiny changes in the amino acid of SARS-CoV-2 within the target area may cause the failure to test monoclonal antibody or decrease the test sensitivity.
8. When collecting a nasal swab sample, use the nasal swab supplied in the kit.
9. Proper specimen collection, storage and transport are critical to the performance of this test.

[PRODUCT PERFORMANCE INDICATORS]

1. Lowest limit of detection (LOD): S1~S4 are positive for SARS-COV-2, S5-S6 are positive or negative for SARS-CoV-2.
2. Positive coincidence rate:PC1-PC8 are positive for SARS-CoV-2.
3.Negative coincidence rate:NC1-NC20 are negative for SARS-CoV-2.
4. Repeatability: CV1-CV2 are positive for SARS-CoV-2.
5. Precision between batches: 3 batches of kit are used to test the repeatability, and the corresponding results can meet the requirements for repeatability.
6. Cross reaction: not react with the following pathogens eg.

Human coronavirus 229E	Mycobacterium tuberculosis
Human coronavirus OC43	Pneumocystis jirovecii
Human coronavirus NL63	Streptococcus pyogenes
MERS-coronavirus	Candida albicans
Human coronavirus HKU1	Pooled human nasal wash – representative of normal respiratory microbial flora
Adenovirus (e.g. C1 Ad. 71)	
Human Metapneumovirus	
Parainfluenza virus 1-4	Bordetella pertussis
Influenza A & B	Mycoplasma pneumoniae
Enterovirus	Chlamydia pneumoniae
Respiratory syncytial virus	Legionella pneumophila
Rhinovirus	Staphylococcus aureus
Haemophilus influenzae	Staphylococcus epidermidis
Streptococcus pneumoniae	

7. Sensitivity and Specificity

300 clinical case samples shich include 62confirmed as COVID-19 positive and 238 confirmed as COVID-19 negative by PCR assay.We are obtained for testing,the results are shown below.

Reagents		PCR		Total
		Positive	Negative	
Vazyme	Positive	57	7	64
	Negative	5	231	236
Total		62	238	300

Sensitivity:91.94%(95%CI:82.47%~96.51%)
Specificity:97.06%(95%CI:94.05%~98.57%)
Total agreement:96.00%(95%CI:93.14%~97.70%)