Virusee® SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)
Instruction for Use

only for in vitro diagnostic and professional use

Please read this IFU carefully before use!

[Name]

SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)

[Model/Specifications]

VSLFA-01/1 test/kit, VSLFA-20/20 tests/kit

[Intended Use]

The SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) is a colloidal gold method intended for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigens in saliva, nasopharyngeal swab and oropharyngeal swab from individuals who are suspected of SARS-CoV-2 infection by their healthcare provider.

Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results do not rule out of SARS-CoV-2 infection and should not be used as the sole basis for treatment patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary, for patient management.

The SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) is intended for use by trained clinical laboratory personnel specifically instructed and trained in vitro diagnostic procedures.

For in vitro diagnostic use only. For professional use only.

[Summary]

The novel coronaviruses (SARS-CoV-2) belong to the β-genus. COVID-19 is an acute respiratory infections disease. People are generally susceptible. Currently, the patients infected by the novel coronaviruses are the main source of infection, asymptomatic infected people can also be one. 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.

[Principle]

SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) adopts a colloidal gold method based on the principle of the double antibody-sandwich technique. It is designed to detect nucleocapsid protein antigen from the SARS-CoV-2 in saliva, nasopharyngeal swab and oropharyngeal swab, from patients who are suspected of SARS-CoV-2 infection.

During testing, the specimen migrates upward under capillary action. The SARS-CoV-2 antigens, if present in the specimen, will bind to the anti- SARS-CoV-2 nucleocapsid protein monoclonal antibody-colloidal gold complex formed immune complex，the immune complex is then captured on the membrane by the pre-coated SARS-CoV-2 nucleocapsid protein monoclonal antibody coated on the T-line., and a visible colored line will show up in the test line region indicating a positive result. In the absence of SARS-CoV-2 antigens, no colored line will form in the test line region, which indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

[Components]

Model/Specifications	Main components	VSLFA-01 1 test/kit	VSLFA-20 20 tests/kit
SARS-CoV-2 Antigen Detection Cassette	Coating the anti- SARS-CoV-2 nucleocapsid protein monoclonal antibody -colloidal gold complex and chicken IgY antibody-colloidal gold complex on the colloidal gold pad. The test line (T) is coated with anti-SARS-CoV-2 nucleocapsid protein monoclonal antibody, and the control line (C) is coated with goat anti-chicken IgY antibody.	1	20
Sterilized Swab	-	1	20
Saliva Collection Device	-	1	20
Extraction Tube with Extraction Reagent	Phosphate buffer solution	300μL×1	300μL×20
Dropper Tip	-	1	20
Package Insert	-	1	1

Note: Components in different batch kits are not interchangeable.

Materials Required but Not Provided: Timer

[Storage Conditions and Validity]

Store at 2-30℃ in a dry and cool place, valid for 12 months.

The SARS-CoV-2 Antigen Detection Cassette should be used within 1h after taken out from aluminum foil bag.

[Warnings and Precautions]

- For in vitro diagnostic use only.
- For healthcare professionals and professionals at point of care sites.
- Do not use this product as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status of COVID-19.
- Do not use after the expiration date.
- Please read all the information in this leaflet before performing the test.
- The test cassette should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test cassette should be discarded according to federal, state and local regulations.

[Specimen requirements]

Specimens obtained early during symptom onset will contain the highest viral titers; specimens obtained after five days of symptoms are more likely to produce negative results when compared to an RT-PCR assay. Inadequate specimen collection, improper specimen handling and/or transport may yield a falsely negative result. Therefore, training in specimen collection is highly recommended due to the importance of specimen quality for generating accurate test results.

Sample Collection

Saliva Sample　Nasopharyngeal Swab Sample　Oropharyngeal Swab Sample

Saliva Sample

Spit 1- 1.5 mL of CLEAR saliva into the saliva collection device. The device must not touch the mouth, and foam does not count to the saliva sample. Do not eat, drink (even water), smoke, vape, chew gum, or tobacco or take medication for at least 30 minutes before your sample collection.

Nasopharyngeal Swab Sample

Insert the swab through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. Swab should reach depth equal to distance from nostrils to outer opening of the ear. Gently roll the swab. Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the tip is saturated with fluid from the first collection. If a deviated nasal septum or blockage creates difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.

Oropharyngeal Swab Sample

Insert swab into the posterior pharynx and tonsillar areas. Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums.

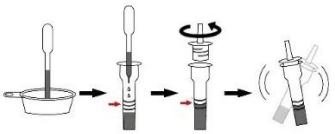
Sample Transport and Storage

Freshly collected specimens should be put into the Extraction Tube with Extraction Reagent as soon as possible, and testing should be performed within one hour.

[Specimen Preparation]

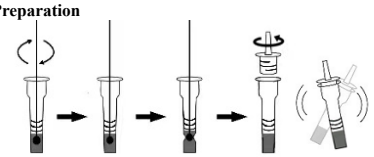
Insert the Extraction Tube into the pre-set hole on the package for fixed placement.

Saliva Sample Preparation



1. Take the saliva sample with a dropper, avoid generating foam in it.
2. Add 8-10 drops (about 300μL) of saliva into the extraction tube to the second mark.
3. Tighten the cap firmly onto the extraction tube.
4. Mix well by swirling the extraction tube at least 20 times.

Swab Sample Preparation



1. Insert the swab sample into the extraction tube which contains extraction reagent.

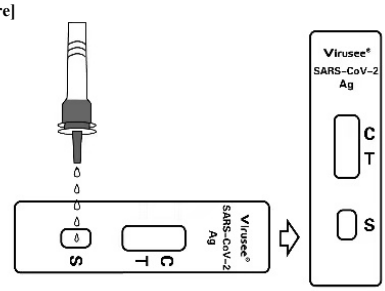
Roll the swab at least 6 times while pressing the head against the bottom and side of the extraction tube.

2. Leave the swab in the extraction tube stand for one minute.

3. Squeeze the sides of the tube to make the liquid immerse the swab. Remove the swab, the extracted solution will be used as test specimen.

4. Tighten the cap firmly onto the extraction tube. Mix well by swirling the tube at least 6 times.

[Test Procedure]



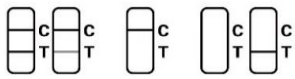
Balance the test device and specimens to room temperature (15-30℃ or 59-86°F) prior to testing.

1. Remove the test cassette from the aluminum foil bag.

2. Reverse the specimen extraction tube, holding the specimen extraction tube up right, transfer 5 drops to the specimen well(S) of the test cassette, then start the timer. See illustration below.

3. Wait for colored lines to appear. Interpret the test results at 15 minutes. Do not read results after 20 minutes.

[Interpretation of results]



Positive: Two lines appear. One colored line should be in the control region (C), and another apparent colored line adjacent should be in the test line (T). Positive for presence of SARS-CoV-2 nucleocapsid protein antigen with patient history and other diagnostic information is necessary to determine infection status Positive results do not rule bacterial infection or co -infection with other viruses. The agent detected may not be the definite cause of disease.

Negative: One colored line appears in the control region (C). No line appears in the test line (T). Negative test results do not preclude infection and should not be used as the sole basis for treatment or other patient management decisions, including symptoms consistent with COVID-19, or in those who have been in contact with virus. It is recommended that these results be confirmed by a molecular testing method, if necessary, for patient management.

Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test cassette. If the problem persists, discontinue using the lot immediately and contact your local distributor.

[Quality Control]

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standard are not supplied with the kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

[Limitations of Detection Method]

The SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) is limited to provide a qualitative detection. The intensity of the test line does not necessarily correlate to the concentration of antigen of specimens.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis of patient management decisions.

A physician must interpret the results in conjunction with the patient's history, physical findings, and other diagnostic procedures.

A negative result can occur if the quantity of antigens for the SARS-CoV-2 virus present in the specimen is below the detection threshold of assay, or the virus has undergone minor amino acid mutation(s) in the target epitope region recognized by the monoclonal antibodies utilized in the test.

Proper specimen collection is critical, and failure to follow the procedure may give inaccurate results, improper specimen storage or repeated freezing and thawing of specimens can lead to inaccurate results.

[Performance Characteristics]

Limit of Detection (Analytical sensitivity)

The Limit of Detection (LoD) of the SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) is $5\times10^{2.50}TCID_{50}$/mL (cultured SARS-CoV-2 virus).

Cross Reactivity (Analytical specificity)

Cross reactivity with following Virus or Bacteria culture with certain concentration has been studied. The results were found negative when tested with the SARS-CoV-2 Antigen Rapid Test (Colloidal Gold):

Virus/Bacteria	Concentration	Results
Influenza A (H1N1)	1×10^6 PFU/mL	-
Influenza A (H3N2)	1×10^6 PFU/mL	-
Influenza B (Yamagata)	1×10^6 PFU/mL	-
Influenza B (Victoria)	1×10^6 PFU/mL	-
Adenovirus	1×10^6 PFU/mL	-
Human metapneumovirus	1×10^6 PFU/mL	-
Parainfluenza virus	1×10^6 PFU/mL	-
Respiratory syncytial virus	1×10^6 PFU/mL	-
Streptococcus pyogenes	1×10^6 CFU/mL	-
Candida albicans	1×10^6 CFU/mL	-
Mycoplasma pneumoniae	1×10^6 CFU/mL	-
Chlamydia pneumoniae	1×10^6 CFU/mL	-
Legionella pneumophila	1×10^6 CFU/mL	-
Human coronavirus 229E	1×10^6 PFU/mL	-
Human coronavirus OC43	1×10^6 PFU/mL	-
Human coronavirus NL63	1×10^6 PFU/mL	-
Human coronavirus HKU1	1×10^6 PFU/mL	-

Clinical Performance

To estimate the clinical performance between the SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) and the PCR comparator, 1020 samples were collected from patients who were suspected of COVID-19.

Summary data as bellow:

		RT-PCR		Total
		Positive	Negative	
SARS-CoV-2 Antigen	Positive	204	6	210
	Negative	8	802	810
Total		212	808	1020

Positive coincidence rate =96.23% (204/212); (95%CI: 92.43-98.23%)

Negative coincidence rate =99.26% (802/808); (95%CI: 98.31-99.70%)

[Symbols Instructions]

CE	CE MARK		KEEP DRY
	CAUTION		BIOLOGICAL RISKS
	CONSULT INSTRUCTIONS FOR USE	LOT	BATCH CODE
	DO NOT REUSE	IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE
	TEMPERATURE LIMITATION		DATE OF MANUFACTURE
	MANUFACTURER	Σ	SUFFICIENT FOR
	KEEP AWAY FROM SUNLIGHT		USE BY
EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY		

[Preparation and Revision Date]

2021.08.02

[Basic information]

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