DIAGREAT

IVD CE

2019-nCoV Antigen Rapid Test Kit (Colloidal gold Assay)

REF Package specification: 1 test/kit, 5 tests/kit or 25 tests/kit

Intended use

It is for professional and in vitro diagnostic use only. 2019-nCoV Antigen Rapid Test Kit (Colloidal gold Assay) is an in vitro immunoassay. The assay is for the direct and qualitative detection of SARS-CoV-2 antigen from nasal swab.

Principle

In the assay, the immuno-colloid gold technique is used to detect antigens (N-protein) of SARS-CoV-2. The reagent binding pad is coated with anti-SARS-CoV-2 monoclonal antibodies, each labeled with a colloid gold marker. A nitrocellulose membrane in the test area of one strip is coated with anti-SARS-CoV-2 antibody. The quality control area within the nitrocellulose membrane is coated with goat anti-mouse IgG antibodies. When tested, the antibodies to SARS-CoV-2 form immune complexes with the N-protein of the virus in the sample being tested. As a result of chromatography, the immune complexes move along the membrane and are captured by the anti-SARS-CoV- 2 antibodies coated in the test area. In doing so, they form a visible red line (T-line). The free colloid gold markers or immune complexes move forward and bind specifically to the goat anti-mouse antibody coated in the quality control area. In doing so, they form a visible line (C-line). If the sample does not contain SARS-CoV-2 antigen, test line will not appear, and only the quality control line (C-line) appears.

Structure of the kit Contents

Test device: There are three different package specifications of 1 or 5 or 25 test cassettes containing immobilized anti-SARS-CoV-2 antibodies labeled with colloid gold, monoclonal anti-SARS-CoV-2 antibodies coated on T line and goat anti-mouse IgG antibodies coated on C line as control

Nasal swabs: 1 or 5 or 25 pieces

Prepacked Extraction Buffer: 500 µl per vial. 1 or 5 or 25 vials.

Note: The sample extraction buffer must not be used with a mixed batch.

Storage and stability

1. Store in dry places and protected from light at 2-30°C. The validity period is 18 months.
2. In general, the kit should be used within 30 minutes after opening the aluminum foil pouch.
3. If the temperature is higher than 30°C or the humidity of the environment is higher than 70%, use the kit as soon as possible after opening the aluminum foil bag.
4. The date of manufacture and the expiry date are printed on the outside of the packaging.

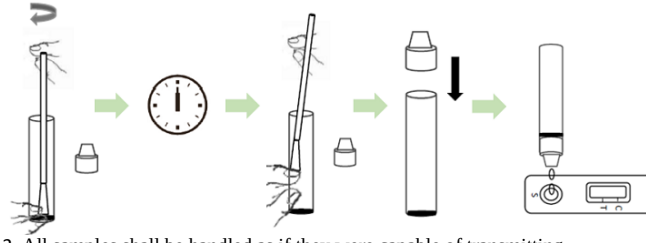
Precautions

- Read these instructions before use. The instructions should to be read carefully and followed.
- Do not use the test kit or its components after the expiration date.
- The device contains material of animal origin and should be treated as a potential biohazard. Do not use if the bag is open or damaged.
- The test devices are sealed in moisture-proof foil pouches. Inspect each foil pouch before opening. Do not use the test if the foil bag is with holes or damaged or not being completely sealed after carefully checking it. Improper storage of test reagents or components may result in erroneous results.
- Do not use the extraction buffer if it is discolored or cloudy. Discoloration or turbidity may be a sign of microbial contamination.
- The user should not take any decision of medical relevance without first consulting his or her medical practitioner.
- Do not reuse the tests.
- After you have done the test, put all parts of the kit in the waste bag. Discard the waste bag in accordance with local regulations
- All patient specimens must be handled and disposed of as if they were biohazardous. Each specimen must be thoroughly mixed with the Specimen Extraction Buffer prior to testing to ensure a representative specimen prior to testing.
- If specimens and reagents are not brought to room temperature prior to testing, assay sensitivity may decrease. If specimens are collected, stored, and transported incorrectly or improperly, false negative test results may occur.
- Avoid skin contact with the buffer.
- If infection with SARS-CoV-2 is suspected based on current clinical and epidemiological testing criteria recommended by public health authorities, samples shall be collected using appropriate precautions to prevent infection and sent to state or local public health authorities for testing.
- Except in a BSL3 laboratory operating in accordance with BSL3 practice, the Virus isolation in cell culture and initial characterization of viral pathogens obtained in cultures of SARS-CoV-2 samples are NOT recommended.

Sample collection and storage

1. Sampling:
   Pour the entire dilution buffer from the buffer vial into the buffer tube.
   Nasal swab: The nasal cavity must be moist. Carefully insert the swab into one nostril of the patient. Insert swab tip 2-4 cm until resistance is encountered. Rotate swab 5 times along nasal mucosa to ensure that both mucus and cells are picked up. Repeat procedure with the same swab in the other nostril to ensure adequate sample is collected from both nasal cavities. Pull the swab out of the nasal cavity.

Sample handling: Dip the head of the cotton swab into the extraction buffer tube after sampling. Mix well and squeeze the cotton swab 10-15 times by pressing the tube wall against the cotton swab. Allow the swab to stand for 1 minute to ensure as many samples as possible in the sample extraction buffer. Discard the cotton swab.



2. All samples shall be handled as if they were capable of transmitting infectious agents.
3. Swabs should be tested as soon as possible after collection. Fresh specimens should be used for optimal testing.
4. Do not use specimens that are obviously contaminated with blood, as this may interfere with specimen flow when interpreting test results.

Quality Control

2019-nCoV Antigen Rapid Test Kit has built-in (procedural) controls. Each test device has an internal standard zone to ensure proper sample flow. The user must verify that the colored line in the "C" region is visible before reading the result.
Best laboratory practice recommends testing positive and negative external controls to ensure that the test reagents are working and the test is being performed correctly.

Test procedure

1. Preparation

a) Adjust the kit to room temperature and make sure the room temperature is 2-30℃ .

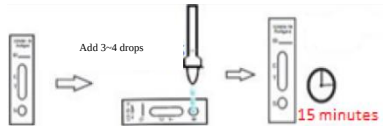
b) Open the packaging bag, take out the cassette and put it out on a dry surface.

2. Test procedure

2.1 Place the test set horizontally on the table.

2.2 Add sample.
Place a clean dropper tip on the sample tube. Invert the test tube so that it is perpendicular to the sample hole (S). Add 3~4 drops (approximately 100 µl) to the sample hole (S). Set the timer to 15 minutes.

2.4 Read the result.
Positive samples can be detected in 15 minutes after sample addition. Result is invalid after 20 minutes.



Interpretation of the results

POSITIVE: Two colored lines appear on the membrane. One line appears in the control region (C), and the other line appears in the test region (T).
NEGATIVE: Only a single colored line appears in the control region (C). No visible colored line appears in the test region (T).
INVALID: The control line does not appear. Discard results from tests that do not show a control line at the specified reading time. Review the procedure and retest with a new test. If the problem persists, discontinue use of the kit immediately and contact your local distributor.
NOTICE:

1. The color intensity in the test region (T) may vary depending on the concentration of analytes present in the sample. Therefore, any staining in the test region should be considered positive. It should be noted that this is only a qualitative test and cannot determine the concentration of analytes in the sample. Insufficient sample volume, incorrect procedures, or expired tests are the most likely reasons for control line failure.

Restrictions

1. This product is for testing samples of individual nasal swab only.
2. A negative result does not exclude the possibility of COVID-19 infection.
3. The test results of this product are for clinical reference only and should not be used as the sole basis for clinical diagnosis and treatment. Clinical management of patients should be determined in combination with their symptoms and signs, medical history, other laboratory tests (especially pathogen detection), response to treatment, epidemiology, and other information.
4. The 2019-nCoV Antigen Rapid Test Kit is intended for self-testing and may only be used for the qualitative detection of SARS-CoV- 2 antigens. The color intensity of a positive line must not be evaluated as "quantitative or semi-quantitative".
5. 2019-nCoV Antigen Rapid Test Kit can be used to detect both viable and non-viable SARS CoV-2 viruses.
6. Failure to follow the TEST PROCEDURE and RESULT INTERPRETATION may affect test performance and/or invalidate the test result.
   Results obtained with this assay, especially in the case of weak test lines that are difficult to interpret, should be used in conjunction with other clinical information available to the clinician.

Features

CLINICAL EVALUATION:

A clinical evaluation was performed to compare results obtained with the 2019-nCoV Antigen Test Kit and RT-PCR. The results are summarized below:

Table 1: Antigen rapid test compared to RT-PCR

Test results	Clinical diagnosis (PCR results)		
	Positive (+)	Negative (-)	Total
Positive (+)	217	0	217
Negative (-)	8	459	467
Total	225	459	684

Clinical Sensitivity: 96.44% (93.11%-98.45%)*
Clinical Specificity: 100% (99.20%-100%)*
Overall Coincidence Rate: 96.62% (94.98%-97.84%)*
95% confidence interval

DETECTION LIMIT

The LoD of Rapid Antigen Test is at Ct 30.1.

PRECISION

Repeatability

Three different QC samples including negative control, weak positive control and morderate positive control were tested using 3 different batches of the product and each sample was tested 6 times obtained on the same testing day by different operators to validate the repeatability of the product.
The Rapid Antigen Test showed good repeatibility on test results by different operators and on the same testing day.

Reproducibility

Three different QC samples including negative control, weak positive control and morderate positive control were tested using 3 different batches of the product and each sample was tested 10 times obtained on the different testing days by different operators to validate the reproducibility of the product.
The Rapid Antigen Test showed good reproducibility on test results by different operators and on the different testing days.

CROSS-REACTIVITY

The Rapid Antigen Test has no cross-reactivities with microbes tested below. Besides, positive test results are not interfered by these microbes.

Table 2: Cross-reactivity

Microbes	Concentration	Microbes	Concentration
HCoV-229E	1E6 PFU/mL	Enterovirus	1E6 PFU/mL
HCoV-OC43	1E6 PFU/mL	Respiratory syncytial virus	1E6 PFU/mL
HCoV-HKU1	1E6 PFU/mL	Rhinovirus	1E6 PFU/mL
HCoV-NL63	1E6 PFU/mL	***Chlamydia pneumoniae***	1E6 PFU/mL
MERS-CoV	1E6 PFU/mL	***Haemophilus influenzae***	1E6 PFU/mL
Adenovirus	1E6 PFU/mL	***Legionella pneumophila***	1E5 CFU/mL
Human Metapneumovirus	1E6 PFU/mL	***Mycobacterium tuberculosis***	1E5 CFU/mL
Parainfluenza virus 1	1E6 PFU/mL	***Streptococcus pneumoniae***	1E5 CFU/mL
Parainfluenza virus 2	1E6 PFU/mL	***Streptococcus pyrogenes***	1E5 CFU/mL
Parainfluenza virus 3	1E6 PFU/mL	***Bordetella pertussis***	1E5 CFU/mL
Parainfluenza virus 4	1E6 PFU/mL	***Mycoplasma pneumoniae***	1E5 CFU/mL
Influenza A	1E6 PFU/mL	***Pneumocystis jirovecii***	1E5 CFU/mL
Influenza B	1E6 PFU/mL	Human nasal wash	33%

INTERFERING SUBSTANCES

The following substances, which may be occurring in breath specimens or artificially introduced into the respiratory tract, were evaluated at the concentrations listed below. None of them were found to interfere with the test performance of the 2019-nCoV Antigen Rapid Test Kit.

Table 3: Substances that did not affect the kit

Group	Substance	Final Conc.
Endogenous interfering substance	Mucin	1%
	Human blood	1%
	Biotin	0.1%
Nasal Spray	BEGGI	1%
	MOREBENDO	1%
	S-O-S	1%
Nasal Corticosteroids Spray	Rhinocort	1%
	Rhinisany	1%
	NASONEX	1%
	Flixonase	1%
Nasal Gel	NeilMed	1%
	Rhinase	1%
	Ayr	1%
Oral Anaesthetic and Analgesic	Mucinex	1%
	HALLS Relief	1%
	LHM	1%
Anti-viral Drugs	Ribavirin	1%
	Oseltamivir	1%
	Zanamivir	1%
	Amantadine	1%
	a- interferon	1%

HooK effect

Within the titer range of clinically strong positive samples of SARS-CoV-2 antigens, there is no hook effect in the test results of this product.

Ordering information

Beijing Diagreat Biotechnologies Co., Ltd
Floor 1-3, Building 19, No. 2 Yard, Huanke Middle Road, Tongzhou District, Beijing, China.
Website: www.diagreat.com Email: info@diagreat.com

EC REP MedNet GmbH
Borkstrasse 10 , 48163 Muenster , Germany

Disposable Cotton Swab manufacturer information:

Taizhou Sun Trine Biotechnology Co., Ltd.
No.420 Jianggao Avenue, Medical High-tech Zone, Taizhou City, Jiangsu Province, China.
Tel: +86523 86161266 Fax: +86 523 8616 1266 www.suntrine.com

EC REP SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands.

Legend for the symbols

	Caution		**Protect from sunlight**
	Manufacturer	LOT	**Batch number**
	Follow the instructions for use	2	**Not reuse**
	Protect from moisture		**Expiration date**
REF	**Catalog number**	IVD	**In vitro diagnostics**
	Do not use if the packaging is open or damaged	2℃ 30℃	**Temperature limits (2-30℃)**
CE 1434	**EU conformity**	EC REP	**Authorized representative**
	Production date		

Version NO.:03 Revision Date:2021.09.17