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

INSTRUCTION FOR USE

INTENDED USE

The SARS-CoV-2 Antigen Test Kit is a gold immuno-chromatographic assay (GICA) that is intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal (NP) swab, nasal (NS) swab, and saliva specimens directly from individuals who are suspected of COVID-19 by their healthcare provider, with or without signs and symptoms of COVID-19.

The SARS-CoV-2 Antigen Test Kit does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. The antigen is generally detectable in upper respiratory specimens during the acute phase of infection. 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 the disease.

If necessary, negative results should be treated as presumptive and confirmed with a molecular assay for patient management. Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or 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.

The SARS-CoV-2 Antigen Test Kit is intended for use by trained clinical laboratory personnel and individuals trained in point of care settings.

GENERAL INFORMATION

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. 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. The median incubation time is estimated to be 5.1 days with symptoms expected to be present within 12 days of infection. The symptoms of COVID-19 are similar to other viral respiratory diseases including fever, cough, and shortness of breath.

PRINCIPLE OF THE TEST

The SARS-CoV-2 Antigen Test Kit is a rapid lateral flow immuno-chromatographic sandwich assay to directly detect nucleocapsid protein of SARS-CoV-2 in the nasopharyngeal swab, nasal swab, and saliva specimens and diagnosis of SARS-CoV-2 infection.

The patient sample is placed in the Sample Tube, during which time the virus particles in the sample are disrupted, exposing internal viral nucleoproteins. After disruption, the sample is added to the Test Cassette sample well. And the sample migrates through a test strip, if the SARS-CoV-2 virus antigen is present, a red color line will be shown on the T line. If the SARS-CoV-2 viral antigen is absent, there is not a red line that will be shown on the T line, however, a red line will be always shown on the C line indicating that the reaction system properly happens.

REAGENTS AND MATERIALS PROVIDED

Item	Components	Specification/Qty.	
		1 Test/kit	20 Tests/kit
1	Test Cassette individually foil pouched with a desiccant	1	20
2	Sample Tube, with 0.5 mL sample buffer.	1	20
3	Single packaged NP/NS swab	1	20
4	Instruction for use	1	1

*** Components will be included when customers demand.**

Materials needed but not provided:

Timer or watch.
Vortex
Saliva collection device/cup/bag
1.0/0.3-mL transfer pipette

PRECAUTIONS

1. For in vitro diagnostic use only.
2. Please read this manual carefully before using this test kit. And follow the testing procedures strictly described in the manual. Otherwise, it will lead to incorrect results.
3. Do not use expired reagents.
4. Do not re-use the test kit.
5. All swab samples, used reagents, test cards, and other materials used during testing are considered to be infectious, and personal protection should be done during the experiment.
6. Use of Nitrile, Latex (or equivalent) gloves is recommended when handling patient samples. Wear suitable protective clothing and eye/face protection when handling the contents of this kit.
7. Sample handling and waste disposal must comply with relevant regulations. Wash hands thoroughly after handling.
8. Avoid using visually bloody or overly viscous samples for testing.
9. Do not use components from different batch lots.
10. The sample tube contains a salt solution. If the solution contacts the skin or eye, flush with copious amounts of water.
11. Sample collection and handling procedures require specific training and guidance.

STORAGE AND STABILITY

1. The test device is sensitive to humidity as well as heat.
2. Store kit components at 2-30°C, out of direct sunlight. Kit components are stable until the expiration date printed on the outer box.
3. After unsealing the aluminum foil bag, the test cassette should be used as soon as possible within **Two Hours**.
4. Do not freeze.

SPECIMEN COLLECTION AND PREPARATION

Test specimens immediately after collection for optimal test performance. Inadequate specimen collection or improper sample handling/storage/transport may yield erroneous results. Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) ***https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html***

1. Nasal swab:

To collect a nasal swab sample, carefully insert the swab into the nostril that presents the most secretion under visual inspection. Using gentle rotation, rotate the swab against the wall of the nostril into the patient's nostril to the nasal palate, and then slowly remove it while wiping.

2. Nasopharyngeal swab:

To collect a nasopharyngeal swab sample, carefully insert the swab into the nostril that presents the most secretion under visual inspection. Keep the swab near the septum floor of the nose while gently pushing the swab into the posterior nasopharynx. Rotate the swab several times then remove it from the nasopharynx.

3. Saliva

Collect the saliva specimen 1 mL using a clean collecting device/cup/bag, then take 0.5 mL saliva sample into the sample tube.

SAMPLE TRANSPORT AND STORAGE

Samples should be tested as soon as possible after collection. The nasal or nasopharyngeal swabs are stable for up to 24 hours at room temperature or 2-8°C.

TEST PROCEDURE

Please read the instructions for use carefully before testing, and complete the test in strict accordance with the directions of the manual, otherwise reliable results cannot be guaranteed.

- Open the aluminum foil bag, put the test cassette on a clean, horizontal bench.
- Bring the samples to room temperature prior to assay in case of the samples were stored at 2-8°C.

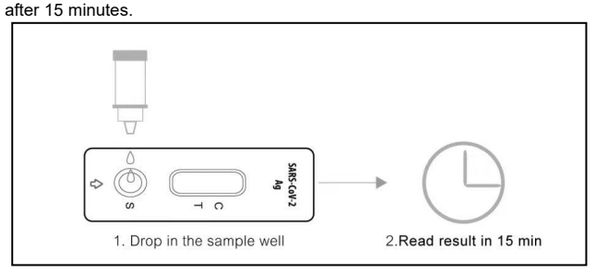
Swab Test Procedure (Nasal/Nasopharyngeal):

1. Place the swab into the sample tube that has been pre-filled with 0.5 mL sample buffer, rotate the swab for about 10 seconds, and press the swab applicator against the tube wall to release the antigen in the swab.
2. Roll the swab applicator against the inside of the sample tube as you remove it. Dispose of the used swab in a biohazard waste following the local government regulations.
3. Install the dropper cap onto the sample tube, add **Two Drops** of the extraction solution into the sample well and start the timer.

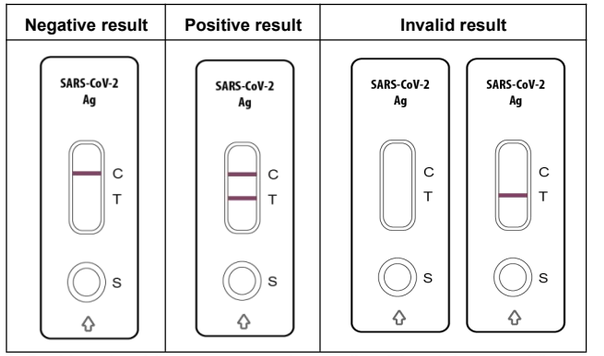
Saliva Test Procedure:

1. Transfer 0.3 mL saliva specimen into the sample tube, vortex to extract the viral antigen in the specimen.
2. Install the dropper cap onto the sample tube, add **Two Drops** of the extraction solution into the sample well and start the timer.

- Read the results within 15 minutes. And the results are invalid after 15 minutes.



INTERPRETATION OF TEST RESULTS



1. Positive: A red line appears on the test line (T) and the control line (C).

NOTE: A positive result does not rule out co-infections with other pathogens.

2. Negative:

Only the control line (C) appears, and no red line appears on the test line (T).

NOTE: A negative result does not exclude infection.

3. Invalid:

There is no red line at the position of the control line (C). Regardless of whether the TEST line (T) is displayed, it is an invalid result and the sample should be tested again.

PERFORMANCES

LoD:

The LoD of the test kit is 10 pg/mL for detection with recombinant SARS-CoV-2 nucleocapsid protein and is 30 $TCID_{50}$ with inactive viral culture.

The Negative Percent Agreement (NPA):

The NPA of the test kit should be 20/20 (-/-) using an internal negative reference panel.

The Positive Percent Agreement (PPA):

The PPA of the test kit should be 8/8 (+/+) using an internal positive reference panel.

Repeatability:

The repeatability of the test kit should be tested using the same batch number, and all of the test results should be positive, and the T lines have even intensities.

ANALYTICAL PERFORMANCE

Limit of Detection (LoD)

The limit of detection (LoD) of the SARS-CoV-2 Antigen Test Kit was determined by evaluating different concentrations of inactivated SARS-CoV-2 virus from viral cell culture and of recombinant nucleocapsid protein (rNp). Tested nasal swab samples were prepared by absorbing 20 uL of each virus or rNp dilution onto the swab. The swab samples were tested according to the test procedure.

The LoD was determined as the lowest virus concentration that was detected ≥ 95% of the time (i.e., the concentration at which at least 20 out of 21 replicates tested positive).

The LoD of the test kit in the nasal swab was confirmed as 30

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$TCID_{50}$/swab and 10 pg/mL of rNp.

LoD Test Results

Concentration	Number: Positive/Total	Detected Percentage
30 $TCID_{50}$/swab	20/21	95%
10 pg/mL	20/21	95%

High Dose Hook Effect

No high dose hook effect was observed when tested with up to a concentration of 3.0x 10^5 $TCID_{50}$/mL of inactivated SARS-CoV-2 virus with the test kit.

Cross-Reactivity

Cross-reactivity of SARS-CoV-2 Antigen Test Kit was evaluated by testing normal respiratory tract pathogenic microorganisms (bacteria, viruses, yeast) and a pooled human nasal wash that may be present in the nasal cavity. Each of the bacteria, viruses, and yeast were tested in duplicate in the absence or presence of heat-inactivated SARS-CoV-2 virus (1.5 x 10^2 $TCID_{50}$/swab). No cross-reactivity or interference came out of these tests when tested at the concentration listed below.

Potential Cross-Reactant		Test Concentration
Virus	Respiratory Syncytial Virus A	1.0 x 10^5 PFU/mL
	Measles Virus	1.0 x 10^5 $TCID_{50}$/mL
	Mumps Virus	1.0 x 10^5 $TCID_{50}$/mL
	Adenovirus Type 3	1.0 x 10^5 $TCID_{50}$/mL
	Parainfluenza Type 2	1.0 x 10^5 $TCID_{50}$/mL
	Partial Pulmonary Virus	1.0 x 10^5 $TCID_{50}$/mL
	Human coronavirus OC43	1.0 x 10^5 $TCID_{50}$/mL
	Human coronavirus 229E	1.0 x 10^5 $TCID_{50}$/mL
	Human coronavirus NL63	1.0 x 10^5 $TCID_{50}$/mL
	MERS coronavirus	1.0 x 10^5 $TCID_{50}$/mL
	Influenza B (Victoria Strain)	1.0 x 10^5 $TCID_{50}$/mL
	Influenza B (Y Strain)	1.0 x 10^5 $TCID_{50}$/mL
	Influenza A (H1N1,2009)	1.0 x 10^5 $TCID_{50}$/mL
	Influenza A (H3N2)	1.0 x 10^5 $TCID_{50}$/mL
	Avian Influenza Virus H7N9	1.0 x 10^5 $TCID_{50}$/mL
	Avian Influenza Virus H5N1	1.0 x 10^5 $TCID_{50}$/mL
	Epstein Barr Virus	1.0 x 10^5 $TCID_{50}$/mL
	Enterovirus CA16	1.0 x 10^5 $TCID_{50}$/mL
	Rhinovirus	1.0 x 10^5 PFU/mL
Bacteria	Staphylococcus aureus	1.0 x 10^6 CFU/mL
	Streptococcus pneumoniae	1.0 x 10^6 CFU/mL
	Mycoplasma pneumoniae	1.0 x 10^6 IFU/mL
	Parapertussis	1.0 x 10^6 cells/mL
	Chlamydia pneumoniae	1.0 x 10^6 IFU/mL
	Pooled human nasal wash	N/A
Yeast	*Candida albicans*	1.0 x 10^6 cells/mL

CLINICAL PERFORMANCES

The clinical performance characteristics of the SARS-CoV-2 Antigen Test Kit were evaluated and a CE marked real-time Polymerase Chain Reaction (RT-PCR) assay for the detection of SARS-CoV-2 was used as the comparison method for this study.

SARS-CoV-2 Antigen Test Kit Performance against the RT-PCR Method

SARS-CoV-2 Antigen Test Kit	Comparison Method (RT-PCR)		
	Positive	Negative	Total
Positive	104	2	106
Negative	4	197	201
Total	108	199	307
Positive Agreement (95% CI): 104/108 96.30% (90.86% - 98.55%)			
Negative Agreement (95% CI): 197/199 98.99% (96.41% - 99.72%)			
Total coincidence rate (95% CI): (104+197)/307 98.05% (95.80% - 99.10%)			

The data below is for understanding information refer to RT-PCR cycle threshold (Ct):

The performance of the SARS-CoV-2 Antigen Test Kit with positive results stratified by the RT-PCR method Ct counts was assessed to more understand the correlation of assay performance to the RT-PCR Ct value, estimating the viral amount present in the clinical sample. As shown in the following table, the positive agreement of the SARS-CoV-2 Antigen Test Kit is higher with samples of a Ct count <33.

Performance against the RT-PCR Method – by Ct Counts

SARS-CoV-2 Antigen Test Kit	RT-PCR Method (Ct)	
	POS (Ct < 33)	POS (Ct ≥ 33)
Positive	95	15
Negative	0	6
Total	95	21
Positive Agreement (95% CI)	100.0 (96.0, 100.0)	71.4 (43.5, 87.4)

Endogenous Interfering Substances

The following interfering substances, that may be introduced into the nasal cavity or nasopharynx, were evaluated with the SARS-CoV-2 Antigen Test Kit at the concentrations listed below and were no effect on the performance of the test kit.

S.N.	Medicine Name	Concentr-ation Tested	S.N.	Medicine Name	Concentr-ation Tested
1	α-Interferon	10 million U/mL	13	Levofloxacin	500 mg/mL
2	Zanamivir	50 mg/mL	14	Azithromycin	1 g/mL
3	Ribavirin	2 g/mL	15	Ceftriaxone	2 g/mL
4	Oseltamivir	200 mg/mL	16	Meropenem	2 g/mL
5	Paramive	1 g/mL	17	Tobramycin	1 g/mL
6	Lopinavir	1 g/mL	18	Phenylephrine	50 mg/mL
7	Ritonavir	250 mg/mL	19	Oxymetazoline	0.5 mg/mL
8	Abidor	1 g/mL	20	Beclomethason	2 mg/mL
9	Dexamethas one	20 mg/mL	21	Flunisolide	5 mg/mL
10	Triamcinolon e acetonide	100 mg/mL	22	Budesonide	2 mg/mL
11	Mometason	1 mg/mL	23	Fluticasone	10 mg/mL
12	Histamine hydro chloride	5 mg/mL	24	Sodium chloride (with preservatives)	10 µg/mL (Benzalkon -ium chloride 50 µg/mL)

LIMITATIONS

1. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
3. Test results must be evaluated in conjunction with other clinical data available to the physician.
4. This test cannot distinguish between asymptomatic carriers and infected persons of the SARS-CoV-2.
5. A false-negative result may be obtained if the concentration of the viral antigen in the specimen (swab/saliva) is below the sensitivity.
6. Negative results should be treated as presumptive and confirmed with an approved molecular assay.
7. Clinical performance was evaluated with frozen samples, and performance may be different with fresh samples.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on SARS-CoV-2 Antigen Test Kit are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and International Standard ISO 15223-1:2016.

Company Information (Specimen Collection Swab)

Hunan Runmei Gene Technology Co., Ltd.

Tel: +86-731-89919680

Registered and manufacturing address: Room 401-1, Building 3, Shanhe Medical and Health Industrial Park, No. 1048, Zhongqing Road, Shaping Street, Kaifu District, Changsha, Hunan Province, P. R. China.

Post code: 410153

EC REP Lotus NL B.V.
Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Company Information (SARS-CoV-2 Antigen Test Cassette)

Shenzhen Uni-medica Technology Co. Ltd

Tel:86-755-86502782 **Fax:** 86-755-86936803

Registered and manufacturing address: Room 202, Block 6th, Liuxian Culture Park, Xili Town, Nanshan District, Shenzhen, Guangdong Province, P. R. China.

Post code: 518055

Website: www.uni-medica.com

EC REP CMC MEDICAL DEVICES & DRUGS S.L.
Address: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain

SYMBOL	DESCRIPTION	SYMBOL	DESCRIPTION
	Manufactured By	CE	CE Mark
EC REP	Authorized Representative	REF	Catalog Number
IVD	In Vitro Diagnostic Medical Device		Potential Biological Hazards After Use
LOT	Batch Code		Do Not Reuse
	Expiration Date in Year-Month-Day Format		Date of Manufacture
	Temperature Limitation		Consult instructions for use
	caution		Keep away from sunlight