SARS-CoV-2 Ag Rapid Test

User instruction manual
For Self-testing
For nasal swab samples
For in vitro diagnostic use

REF RTG0101 / RTG0104 / RTG0102 / RTG0103
1 test / 2 tests / 5 tests / 20 tests

[Intended use]
This assay is based on a colloidal gold method for the rapid, qualitative determination of SARS-CoV-2 (Severe Acute Respiratory Syndrome Coronavirus 2) nucleocapsid protein antigen in anterior nasal swab specimens.
This test kit is intended for self-testing at home for individuals with symptoms of SARS-CoV-2 infection. This test kit shall not be used as a sole basis to diagnose or exclude SARS-CoV-2 infection.

[Summary]
Coronavirus disease 2019 (COVID-19) is a disease caused by a novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2, also known as 2019-nCoV)[1].
Coronaviruses are a large family of single-stranded RNA viruses. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. It is contagious during the incubation period, and it is highly contagious within 5 days after the onset of the disease. The main route of transmission of COVID-19 is through respiratory droplets and close contact. The clinical manifestations of COVID-19 are diverse, ranging from asymptomatic to mild respiratory symptoms such as fever, dry cough, and fatigue, and can also cause severe respiratory disease and even death[2].

[Measurement Principle]
This assay is based upon one-step sandwich method. This test contains a membrane, which is pre-coated with SARS-CoV-2 nucleocapsid protein antibody on the test line and goat anti-mouse IgG on the control line. The samples with SARS-CoV-2 nucleocapsid protein antigen which can specifically bind to colloidal gold labeled with SARS-CoV-2 nucleocapsid protein antibody, and sprayed on conjugation pads. As the complex continues to travel up in the card, the SARS-CoV-2 nucleocapsid protein antigens are bound to the test line. The control (C) line appears when sample has flowed through the card. The presence of SARS-CoV-2 nucleocapsid protein antigen will be indicated by the visible test line (T). Both the Test Line and Control Line in result window are not visible before applying any samples. The control line is used for procedural control and should appear regardless of the test result.The appearance of the control line serves to ensure the test is performing properly and the testresult is valid.

[Materials Provided]

Components	1 test	2 tests	5 tests	20 tests
Extraction Buffer	1	2	5	20
COVID-19 Ag Cassette	1	2	5	20
Disposable Sterile Swab	1	2	5	20
Garbage Bag	1	2	5	20
Instruction for use	1	1	1	1

[Materials Required but not Provided]
1) Timer
2) Personnal protective equipment when handling the contents of this kit for another person

[Warnings and Precautions]
1. For *in vitro* diagnostic use only. For self-testing.
2. This test has been authorized only for the detection of SARS-CoV-2 antigen, not for any other viruses or pathogens.
3. Follow the instruction for use carefully. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.
4. Handle the potentially contaminated materials safely according to local requirement.
5. Unless you are using thetest on yourself,it is recommended that use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of having COVID-19. Wash hands after operations.
6. Wipe and wash the splashed sample with highly effective disinfectant. Avoid splashing and the formation of smog.
7. Decontaminate the dispose of all samples, used kits and potentially contaminated materials as if they were infectious waste,in a garbage bag, throw the garbage bag in the trash, then wash or disinfect your hands.
8. Do not mix and interchange different samples.
9. This kit is for external use. Do not swallow.
10. Use unpacked Cassette as soon as possible to avoid being humidified. The Cassette is sensitive to humidity as well as to heat.
11. Do not use the Cassette beyond the labeled expiry date indicated on the outer container.
12. Do not use the Cassette if the pouch is damaged or the seal is broken.

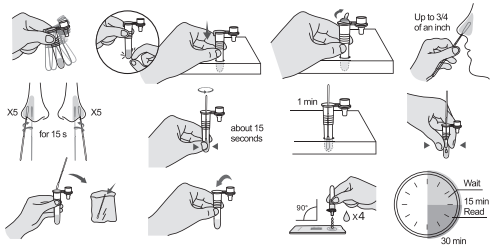
13. The Cassette cannot be reused.
14. The components in different batches cannot be interchanged.
15. Proper sample collection, storage are essential for correct results.

[Storage]
1. Store all components at 2-30℃and protected from direct sunlight. Do not freeze.
2. The Cassette was stable throughout the expiration date printed on outer container. The Cassette should remain in sealed aluminum foiled pouch until ready for use and not freeze. It cannot be used beyond the expiration date.
3. Store Extraction Buffer at 2-30℃ after use, then it can be used until the expiration date.
4. The Cassette shall be used immediately after opening the package, especially in an environment with high temperature or humidity.

[Sample]
1. This test kit can be used to test anterior nasal swabs specimen.
2. Specimens should be collected with appropriate infection control precautions.
3. Insufficient processing of the samples, or disruption of the sample may cause inaccurate results.
4. Freshly collected samples should be directly processed with Extraction Buffer. If the collected swab samples are not detected immediately, the collected swab samples should be stored in the Extraction Buffer provided by this kit at room temprature (15-30℃) for no more than 2 hours.

[Test procedure]
Reagent Preparation
1. Bring all reagents, Cassette to room temperature before testing, ensure them to be completely recovered to room temperature before proceeding to the next step.
2. Wash or disinfect your hands before perfoming the testing process.
3. Take out the Extraction Buffer and remove the Cassette from the aluminum foiled pouch, place them on a clean, flat and dry surface.

Sample preparation and Testing
1. Shake the Extraction Buffer tube 2-3 times, then flick the bottom of the extraction tube. Insert the extraction tube straight into the pre-set hole on the package box.
2. Gentally peel off the aluminum foil seal, and do not spill the liquid inside the tube.
3. Gentally insert the soft end of the swab about 1/2 to 3/4 of an inch into a nostril, slowly rotate against the nasal wall 5 times to approximately 15 seconds. Repeat in the other nostril using the same swab.
4. Withdraw the swab from your nostril. And insert the swab head into the bottom of the tube. While pressing the tube against the swab, rotate the swab for about 15 seconds. Leave the swab inside the tube for 1 minute.
   Note: Risk of a false negative result if these steps are not followed properly.
5. As you remove the swab from the tube, squeeze swab tip from outside of the tube to release as much liquid from the swab as possible. Dispose the swab into the waste bag.
6. Close the dripper firmly.
7. Drip four drops of sample veritically into the sample well on the cassette. And start timing.
8. Read the result between 15 to 30 minutes. Result becomes INVALID after 30 mintutes.



[Waste Disposal]
Disposal all components used as a potential risk of infection.
1) Put the used products and materials in the garbage bag;
2) Throw the garbage bag into the trash;
3) Wash or disinfect your hands.

[Measurement Results]
Positive Reaction
Observe two visible lines, the control line in the control (C) and the test line in the COVID-19 Ag test (T) region of the membrane.

When the result was positive:
- There is currently a suspicion of a COVID-19 infection, contact your doctor/general practitioner or the local health department immediately;
- Comply with local guidelines for self-isolation;
- Have a PCR confirmatory test performed;

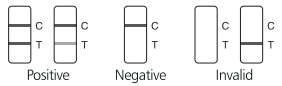
Negative Reaction
If control lines (C) are present in the result windows and no test line appears in

test line region, the test result is negative for the analytes.

When the result was negative:
- Continue to comply with all applicable rules regarding contact with others and adhere to protective measures;
- There may be an infection even if the test is negative;
- In case of suspicion, repeat the test after 1-2 days because the coronavirus cannot be accurately detected in all phases of an infection;

Invalid Reaction
If control lines (C) do not appear, the test result is invalid regardless of the appearance. Some causes of invalid results are not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the sample be re-tested using a new Cassette.

When the result was invalid:
- Possibly caused by incorrect test execution
- Repeat the test
- If the test results are still invalid, contact a doctor or a the COVID-19 test center
- Have a PCR confirmatory test performed



[Control Procedure]
An internal procedural control is included in the test. A visible line appearing in the C line is an internal procedural control. It confirms sufficient sample volume, adequate membrane wicking and correct procedural technique.

[Limitations of the Procedure]
1. This test kit isonly used for thedetection of human anterior nasal swabs. The results of other samples may be incorrect.
2. Thistest kit is limited to the qualitative detection of antigens specific for the SARS-CoV-2 virus. The intensity of the test line does not necessarily correlate to SARS-CoV-2 antigen titer in the specimen. Neither the quantitative value nor the rate of increase in SARS-CoV-2 antigen can be determined by this qualitative test.
3. This test kit is a nauxiliary clinical diagnostic toolonly.If the result is positive, it is recommended to use other methods for further examination inatimely manner, and priorityis given to the doctor's diagnosis.
4. Follow the instruction for use carefully. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions and failure to comply with intepretation results in this package insert.
5. Negative results DO NOT rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
6. Results from antigen testing should NOT be used as the SOLE basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
7. A negative test result may occur when the level of antigen in a sample is below the detection limit of the test, improper sampling, improper transmission or handling the samples, variations of viral genes.
8. Positive results do not differentiate between SARS-CoV and SARS-CoV-2.
9. Positive test results do not rule out co-infections with other pathogens.
10. False positive results for antigen may occur due to cross-reactivity or other possible causes.
11. False negative results may occur if inadequate Extraction Buffer is used.
12. Do not use heat-inactivated samples.
13. Do not use samples extracted or stored in inactivated sampling tubes (containing protein denaturants such as guanidine hydrochloride).
14. This test does not determine the etiology of the respiratory infection caused by micro-organisms other than the SARSCoV-2 virus.
15. A negative result does not rule out infection by the SARS-CoV-2 virus, particularly in people who have come into contact with the virus. Follow-up tests with molecular diagnostics should be scheduled to rule out infection in these people.Persons who show symptoms of the disease but have a negative result until infection is ruled out should follow countryspecific restrictions.

[Performance Characteristics]
1. Limit of Detection

The SARS-CoV-2 positive specimen was prepared by spiking inactivated viral cultures isolated from samples of COVID-19 patients to negative matrix (the collected normal human nasal swab eluted in 0.02M PBS pH 7.4). Samples with different virus titer were tested with SARS-CoV-2 Ag Rapid Test.
The Limit of Detection (LoD) of this assay is $2.1*10^2$ $TCID_{50}$/mL.

2. Cross-reaction

There is no cross reaction with the following pathogens: Influenza A virus, Influenza B virus, Endemic human coronavirus (HKU1, OC43, 229E, NL63), Parainfluenza virus, Rhinovirus, Respiratory syncytial virus, Adenovirus. There is cross reaction with 3.5 μg/mL of SARS-CoV nucleocapsid protein.

3. Interference

Microbial interference: there is no microbial interference with Chlamydia

pneumonia, Mycoplasma pneumonia, Metapneumovirus, Streptococcus pneumonia, Candida glabrata and Haemophilus influenza.
The following substances do not interfere with the results of the kit: 4% of whole blood, 0.5% of mucin, 0.5% Ganmaoling, 1.5mg/mL of throat lozenges (Dyclonine/menthol), 15% of nose drops, 4μg/mL of tobramycin.

4. Clinical performance

In total 566 clinical samples which include 456 confirmed as SARS-CoV-2 negative and 110 confirmed as SARS-CoV-2 positive by PCR were tested with SARS-CoV-2 Ag Rapid Test.The results were as summarized as below:

Reagent		PCR		
		POS	NEG	TOTAL
SARS- CoV-2 Ag Rapid Test	POS	104	0	104
	NEG	6	456	462
Total		110	456	566

Note:
Diagnostic sensitivity = (SARS-CoV-2 Ag positive)/(PCR positive)
Diagnostic specificity= (SARS-CoV-2 Ag negative)/(PCR negative)
Accuracy=(SARS-CoV-2 Ag and PCR negative+ SARS-CoV-2 Ag and PCR positive+)/(PCR negative+PCR negative)
Diagnostic sensitivity:94.55%(104/110)（95%CI, 88.51% -97.97%);
Diagnostic specificity:100.00%(456/456)（95%CI, 99.19% - 100.00%).
Accuracy: 98.94%(560/566) (95%CI, 97.71%-99.61%)

5. HOOK Effect

Virus with concentration of $2.3*10^6$ $TCID_{50}$/mL were tested, there were no false negative results.

[Possibleproblems and solutions]

Possibleproblem	Possible Reason	Solution
The quality control line (line C) is not displayed.	Less sample dripping	Add 1-2 drops of sample again
	Reagent was out of expiry date	Retest
	The sample was too viscous	Resample for testing
Aluminum foil bag is Damaged	Product iscompressed or damaged	Discard the packaged product and re-test
Symptoms are present, but the test result is negative.	The virus concentration in the sample is lower than the lowest detectable concentration.	Please test again after 1-2days.Or test using another method, such as a PCR test.
Symptomsare not present,but the test result is positive.	It may be an asymptomatic infection.	1.Currently suspected of COVID-19 infection
		2.Contact your doctor/ general practitioner or local health department immediately.
		3.Follow local guidelines for self-quarantine.
The sample does not ascend up or the asending process is not smooth	There was too much mucin in the nose during sampling	Resampling and retest the experiment and avoid sticky substances such as nasal mucus on the swab during sampling

[Literature References]
[1] Naming the coronavirus disease (COVID-2019) and the virus that causes ithttps://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-itAccessed March 12, 2020.
[2] Rasmussen A L, Popescu S V. SARS-CoV-2 transmission without symptoms[J]. Science, 371.

[Trademarks]

IVD	in vitro diagnostic medical device		do not reuse
	use by		instructions for use
	temperature limitation	LOT	batch code
REF	catalogue number		protect from moisture
	keep away from sunlight		do not use the product if the packaging is damaged.
	date of manufacture		contains sufficient for <n> tests
	manufacturer	EC REP	authorized representative in the European Community

AUTOBIO DIAGNOSTICS CO., LTD.
No.87 Jingbei Yi Road
National Eco & Tech Development Area
Zhengzhou China 450016

CE 1434 IVD

EC REP OBELIS S.A. Bd.
Général Wahis, 53,
1030 Brussels, Belgium

For any technical assistance please contact us in English at: Email: customerservice@autobio.com.cn