SARS-CoV-2 Ag Rapid Test

Rapid chromatographic immunoassay for the
qualitative detection of SARS-CoV-2 antigens present in human nasopharynx.

For professional in vitro diagnostic use only

Cat. No. **1-367-K020** cassettes: 20 pcs
Cat. No. **1-367-KK20** cassettes: 20 pcs+ positive and negative control swab

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INTENDED USE

The SARS-CoV-2 Ag Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigens in nasopharyngeal swab specimens from individuals with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests.
Results are for the detection of SARS-CoV-2 Antigens. An 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 coinfection with other viruses. The agent detected may not be the definite cause of disease. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions. Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary for patient management. 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 Ag Rapid Test is intended for use by trained clinical laboratory personnel.

SUMMARY

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. 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

The COVID-19 Antigen Rapid Test (Nasopharyngeal Swab) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 nucleocapsid protein antigens in human nasopharyngeal swab specimen. SARS-CoV-2 antibody is coated in the test line region. During testing, the specimen reacts with SARS-CoV-2 antibody-coated particles in the test. The mixture then migrates upward on the membrane by capillary action and reacts with the SARS-CoV-2 antibody in test line region. If the specimen contains SARS-CoV- 2 Antigens, a colored line will appear in test line region as a result of this. If the specimen does not contain antigens to SARS-CoV-2, no colored line will appear in the test line region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

PRECAUTIONS

1. This package insert must be read completely before performing the test. Failure to follow directions in package insert may yield inaccurate test results.
2. For professional *in vitro* diagnostic use only. Do not use after expiration date.
3. Do not eat, drink or smoke in the area where the specimens or kits are handled.
4. Do not use test if pouch is damaged.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout in the collection, handling, storage, and disposal of patient samples and used kit contents.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Wash hands thoroughly after handling.
8. Please ensure that an appropriate amount of samples are used for testing. Too much or too little sample size may lead to deviation of results.
9. Viral Transport Media (VTM) may affect the test result; extracted specimens for PCR tests cannot be used for the test.
10. The used test should be discarded according to local regulations.
11. Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.**

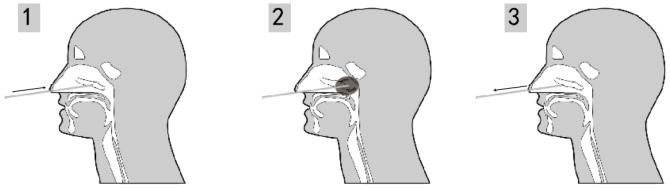
MATERIALS PROVIDED

1-367-K020		**1-367-KK20**	
Test cassettes	20 pcs	Test cassettes	20 pcs
Extraction buffer	20 pcs	Extraction buffer	20 pcs
Extraction tubes with tips	20 pcs	Extraction tubes with tips	20 pcs
Nasopharyngeal swab	20 pcs	Nasopharyngeal swab	20 pcs
Package insert	1 pc	Package insert	1 pc
-		Positive control swab	1 pc
-		Negative control swab	1 pc

SPECIMEN COLLECTION AND PREPARATION

Specimen Collection

1. Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx.
2. Rotate the swab 5 times or more against the nasopharyngeal wall.
3. Withdraw the sterile swab from the nasal cavity.



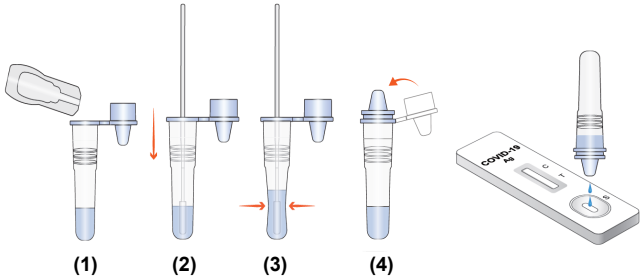
Specimen transport and storage

Specimens should be tested as soon as possible after collection.
If swabs are not been processed immediately, it is highly recommended the swab sample is placed into a dry, sterile, and tightly sealed plastic tube for storage. The swab specimen in dry and sterile condition is stable for up to 1 hour at room temperature.

SPECIMEN PREPARATION

Only the extraction buffer and tubes provided in the kit is to be used for swab specimen preparation.

1. Twist off the head of the buffer, dispense all the buffer into the extraction tube (1)
2. Insert the swab into the extraction tube containing extraction buffer. Rotate the swab at least 60 seconds while pressing the head against the bottom and sides of the extraction tube (2).
3. Remove the swab while squeezing the swab head against the inside of the Extraction Tube as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol (3).
4. Fit the dropper tip on top of the extraction tube (4).



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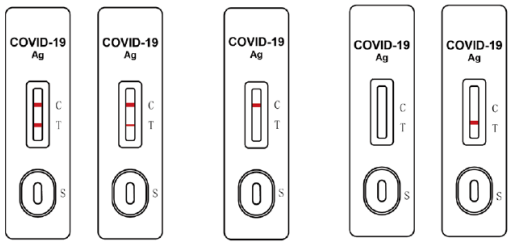
TEST PROCEDURE

Allow the test, extracted specimen and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed foil pouch.
2. Invert the specimen extraction tube and add **2 drops of extracted specimen** to the specimen well(S) and then start the timer.
3. Wait for the colored line(s) to appear. Read the result at **10 minutes**. Do not interpret the result after 20 minutes.



Positive Negative Invalid

INTERPRETATION OF RESULTS

POSITIVE:* Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T).
Positive result in the test region indicates detection of SARS-COV-2 nucleocapsid protein antigens in the sample.
***NOTE**: The intensity of the color in the test line region (T) will vary based on the amount of SARS-COV-2 antigen present in the sample. So any shade of color in the test region (T) should be considered positive.
NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test line region (T).
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 with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal Quality Control

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative procedural control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

External Quality Control

Positive and negative controls are included in kit Cat. No.1-367-KK20. In compliance with Good Laboratory Practice (GLP), these controls are recommended.

LIMITATIONS

1. The test Procedure and the Interpretation of test Result must be followed closely when testing for the presence of SARS-CoV-2 nucleocapsid protein antigens in the human nasopharyngeal specimens from suspected individuals. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
2. Viral Transport Media (VTM) may affect the test result; extracted specimens for PCR tests cannot be used for the test.
3. The SARS-CoV-2 Ag Rapid Test (Nasopharyngeal swab) is for *in vitro* diagnostic use only. This test should be used for detection of SARS-CoV-2 Antigens in human nasopharyngeal specimens as an aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests. Neither the quantitative value nor the rate of increase in the concentration of SARS-CoV-2 antigens can be determined by this qualitative test.
4. If the test result is negative or non-reactive and clinical symptoms persist. It is recommended to re-sample the patient a few days later and test again or test with a molecular diagnostic device to rule out infection in these individuals.
5. The test will show negative results under the following conditions: The concentration of the novel coronavirus antigens in the sample is lower than the minimum detection limit of the test.
6. 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.
7. Excess blood or mucin on the swab specimen may interfere with test performance and may yield a false positive result.
8. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
9. Negative test results are not intended to rule in other non-SARS viral or bacterial infections.

PERFORMANCE CHARACTERISTICS

Sensitivity, Specificity and Accuracy

The SARS-CoV-2 Rapid Test (Nasopharyngeal Swab) has been evaluated with specimens obtained from the patients. RT-PCR is used as the reference method for the COVID-19 Antigen Rapid Test (Nasopharyngeal Swab). Specimens were considered positive if RT-PCR indicated a positive result. Specimens were considered negative if RT-PCR indicated a negative result.

		RT-PCR		Total Results
SARS-CoV-2 Ag Rapid Test	Results	Positive	Negative	
	Positive	110	2	112
	Negative	5	209	214
Total Results		115	211	326
Diagnostic Sensitivity: 95.7% (95%CI*: 90.2% ~ 98.1%)				
Diagnostic Specificity: 99.1% (95%CI*: 96.6% ~ 99.7%)				

* Confidence Intervals

Detection Level

SARS-CoV-2 Ag Rapid Test LOD was confirmed as 1.6 x10^2 $TCID_{50}$/mL.

Precision

Intra-Assay & Inter-Assay

Within-run and Between-run precision has been determined by using three specimens of COVID-19 standard control. Three different lots of SARS-CoV-2 Ag Rapid Test have been tested using negative sample, critical positive sample and positive sample for testing. Two operators use three batches of kits for 5 days. Five replicates of each level were tested each day. The specimens were correctly identified > 99% of the time.

Cross-reactivity

No false positive SARS-CoV-2 test results were observed on specimens from the following disease states or specific conditions, respectively.

Human Coronavirus HKU1	Adenovirus (ADV) Type 4
Human Coronavirus OC43	Adenovirus (ADV) Type 5
Human Coronavirus NL63	Adenovirus (ADV) Type 7
Human Coronavirus 229E	Adenovirus (ADV) Type 55
New Type H1N1 Influenza Virus (2009)	HRV
Seasonal H1N1 influenza virus	Enterovirus group A
H3N2	Enterovirus group B
H5N1	Enterovirus group C
H7N9	Enterovirus group D
Yamagata positive sample for influenza B	MAE
Influenza B Victoria positive sample	Mycoplasma pneumoniae
Rhinovirus Group A positive samples	Candida albicans
Rhinovirus group B positive samples	Normal sample
Rhinovirus Group C positive samples	HAV
Human cytomegalovirus virus positive sample	HBV
Norovirus positive samples	HCV
Mumps virus positive sample	HEV
Varicella-zoster virus positive sample	HIV
Respiratory syncytial virus (RSV)	TB
Epstein-Barr virus	Dengue
Adenovirus (ADV) Type 1	Helicobacter pylori
Adenovirus (ADV) Type 2	MERS
Adenovirus (ADV) Type 3	

BIBLIOGRAPHY

1. Westgard JO, Barry PL,Hunt MR, Groth T. A multi-rule Shewhart for quality control in clinical chemistry, Clinical Chemistry 1981;27:493-501

GRAPHICAL SYMBOLS USED:

REF - Catalogue number
LOT - Lot number
IVD - For in vitro diagnostic use only
- Use by
- Consult instructions for use
- Do not use if package is damaged
- Store between
- Manufacturer