COVID-19 Antigen Rapid Test Device

COV-S23

in vitro diagnostic use only.

INTENDED USE

COVID-19 Antigen Rapid Test Device is an in vitro immunoassay. The assay is for the direct and litative detection of SARS-CoV-2 viral nucleoprotein antigens from nasal and nasopharyngeal imens collected from individuals with (within the first 5 days of symptom onset) or without mptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three with at least 24 hours but not more than 36 hours between tests.

COVID-19 Antigen Rapid Test Device is intended for use by trained healthcare professionals. For tory and point of care use. This assay is not intended for home testing (or self-testing).

ults are for the identification of SARS-CoV-2 viral nucleoprotein antigen. Antigen is generally ctable in nasal and nasopharyngeal secretions during the acute phase of infection. Positive results ate the presence of viral antigens, but clinical correlation with patient history and other diagnostic rmation is necessary to determine infection status. Positive results do not rule out bacterial infection o-infection with other viruses. The agent detected may not be the definite cause of disease. ratories are required to report all positive results to the appropriate public health authority.

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

SUMMARY AND EXPLANATION OF THE TEST

onaviruses are a large family of viruses that are common in many different species of animals, uding camels, cattle, cats, and bats.

virus is transmitted mainly via respiratory droplets that people release, cough, or exhale. The ation period for COVID-19 is currently estimated at between 2 and 14 days. Common symptoms OVID-19 infection include fever, cough and respiratory symptoms such as shortness of breath and ing difficulties. More serious cases develop severe pneumonia, acute respiratory distress rome, sepsis and septic shock that can lead to the death of the patient. People with existing chronic itions seem to be more vulnerable to severe illness.

ople with COVID-19 are tested and diagnosed in a timely manner and rigorous infection control sures are applied, the likelihood of sustained human-to-human transmission in community settings is

PRINCIPLE

COVID-19 Antigen Rapid Test Device detects SARS-CoV-2 viral antigens through visual pretation of color development. Anti-SARS-CoV-2 antibodies are immobilized on the test region of nitrocellulose membrane. Anti-SARS-CoV-2 antibodies conjugated to colored particles are ybilized on the conjugated pad. A sample is added to the extraction buffer which is optimized to ase the SARS-CoV-2 antigens from specimen.

g testing, the extracted antigens bind to anti-SARS-CoV-2 antibodies conjugated to colored cles. As the specimen migrates along the strip by capillary action and interacts with reagents on the brane, the complex will be captured by the anti-SARS-CoV-2 antibodies at the test region. Excess ed particles are captured at the internal control zone.

presence of a colored band in the test region indicates a positive result for the SARS-CoV-2 viral en, while its absence indicates a negative result. A colored band at the control region serves as a ernal control, indicating that the proper volume of specimen has been added and membrane ing is working.

MATERIALS

Materials Provided

- Individually packed test devices
- Individually packed swabs
- Package insert
- Negative control(If required)
- Extraction buffer
- Tube stand
- Positive control(If required)

Materials Required but Not provided

Clock, timer or stopwatch

PRECAUTIONS

For in vitro Diagnostic Use Only.

This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.

Read the Package Insert prior to use. Directions should be read and followed carefully.

- Do not use kit or components beyond the expiration date.
- Specific training or guidance is recommended if operators are not experienced with specimen collection and handling procedures. Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when specimens are collected and evaluated.
- The device contains material of animal origin and should be handled as a potential biohazard. Do not use if pouch is damaged or open.
- Test devices are packaged in foil pouches that exclude moisture during storage. Inspect each foil pouch before opening. Do not use devices that have holes in the foil or where the pouch has not been completely sealed. Erroneous result may occur if test reagents or components are improperly stored.
- Do not use the Extraction Buffer if it is discolored or turbid. Discoloration or turbidity may be a sign of microbial contamination.
- All patient specimens should be handled and discarded as if they are biologically hazardous. All specimens must be mixed thoroughly before testing to ensure a representative sample prior to testing.
- Failure to bring specimens and reagents to room temperature before testing may decrease assay sensitivity. Inaccurate or inappropriate specimen collection, storage, and transport may yield false negative test results.
- Avoid skin contact with buffer.
- If infection with SARS-CoV-2 is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions and sent to state or local health departments for testing.
- Viral isolation in cell culture and initial characterization of viral agents recovered in cultures of SARS-CoV-2 specimens are NOT recommended, except in a BSL3 laboratory using BSL3 work practices.

STORAGE AND STABILITY

- Store The COVID-19 Antigen Rapid Test Device at 2-30℃ when not in use.
- **DO NOT FREEZE.**
- Kit contents are stable until the expiration dates marked on their outer packaging and containers.

SPECIMEN COLLECTION AND STORAGE

-Nasopharyngeal swab (NP swab):

1) Remove the swab from its packing.
2) Insert the swab into the nostril parallel to the palate. Rotating against the nasal wall. (to ensure swab contains cells as well as mucus)
3) Process the swab as soon as possible after collecting the specimen.

-Nasal swab (NS swab)

1) Remove the swab from its packing.
2) Put the swab gently into nostril (about 1-2cm up your nose). Roll the swab firmly around the inside of the nostril, making 5 complete circles. Repeat this process for the other nostril to ensure that an adequate Specimen is collected from both nasal cavities. (use the same swab)
3) Process the swab as soon as possible after collecting the specimen.

a) Nasopharyngeal swab b) Nasal swab

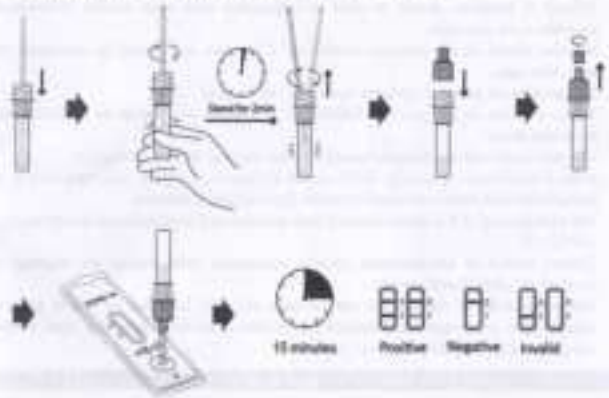
Note:

1. Use only synthetic fiber swabs with plastic shafts. Do not use calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit further testing.
2. Swabs specimens should be tested as soon as possible after collection. Use freshly collected specimens for best test performance.
3. If not tested immediately, swab specimens may be stored at 2-8℃ for 24 hours after collection.
4. Do not use specimens that are obviously contaminate with blood, as it may interfere with the flow of sample with the interpretation of test results.

TEST PROCEDURE

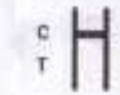
Bring devices, reagents and specimens and/or controls to room temperature (15-30℃) before use.

1. For each specimen, open the foil pouch just before testing and remove the test device, and put it on a clean, level surface. Label the tube with the patient identification. For best results, the assay should be performed within one hour.
2. Take off the blue cap of the extraction tube and insert the swab into the extraction tube. Mix well and squeeze the swab 10-15 times by compressing the walls of the tube against the swab.
   Stand for 2 minutes.
3. Roll the swab head against the inner wall of the tube as you remove it. Try to release as much liquid as possible. Dispose of the used swab in accordance with your biohazard waste disposal protocol.
4. Place the blue cap back to the extraction tube. Unscrew the white cap and add 3 drops of solution into the sample well by gently squeezing the tube.
5. Read results at 15 minutes. Do not interpret the result after 30 minutes.



RESULT INTERPRETATION

POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).



NEGATIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The color intensity in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

Internal Procedural Controls

The COVID-19 Antigen Rapid Test Device has built-in (procedural) controls. Each test device has an internal standard zone to ensure proper sample flow. The user should confirm that the colored band located at the "C" region is present before reading the result.

External Positive and Negative Controls

Positive and negative control should be tested to ensure the proper performance of the assay. It is recommended to test these positive and negative controls when a new lot of tests is open. When performed properly, in addition to the presence of C line, no line should be visible for the negative control and the T line is visible for the positive controls. Additional controls may be qualified and tested by the user.

LIMITATIONS OF THE TEST

1. The COVID-19 Antigen Rapid Test Device is for professional *in vitro* diagnostic use, and should only be used for the qualitative detection of SARS-CoV-2 antigen. The intensity of color in a positive band should not be evaluated as "quantitative or semi-quantitative".
2. Both viable and nonviable SARS-CoV-2 viruses are detectable with The COVID-19 Antigen Rapid Test Device.
3. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

Failure to follow the TEST PROCEDURE and RESULT INTERPRETATION may adversely affect test performance and/or invalidate the test result.

Results obtained with this assay, particularly in the case of weak test lines that are difficult to interpret, should be used in conjunction with other clinical information available to the physician.

Negative results do not preclude SARS-CoV-2 infection and should be confirmed via molecular assay.

This assay is not intended for home testing (or self-testing).

Negative results do not preclude SARS-CoV-2 infection and should be confirmed via molecular assay.

This test cannot rule out diseases caused by other bacterial or viral pathogens.

If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.

The performance of this device has not been assessed in a population vaccinated against COVID-19.

Clinical studies in asymptomatic patients undergoing serial testing are ongoing to establish the clinical performance.

The performance of this test has not yet been clinically validated for use in patients without signs and symptoms of respiratory infection or for serial screening applications, and performance may differ in these populations.

PERFORMANCE CHARACTERISTICS

nal Performance:

e 1: With nasopharyngeal Swab as a sample type

performance of the COVID-19 Antigen Rapid Test Device was established with 230 direct pharyngeal swabs collected and enrolled from individual symptomatic patients who were ected of COVID-19. Three (3) sites across the United States participated in the study. The mens were tested fresh by minimally trained operators, and FDA EUA RT-PCR assay for tection of SARS-CoV-2 was utilized as the comparator method for the study.

mary of the Performance of the COVID-19 Antigen Rapid Test Device Compared to RT-PCR

COVID-19 Antigen Rapid Test	RT-PCR		Total
	Positive	Negative	
Positive	50	5	55
Negative	3	174	177
Total	53	177	230
Positive Percent Agreement (PPA)	94.3 % (95% CI: 84.6% – 98.1%)		
Negative Percent Agreement (NPA)	98.3 % (95% CI: 95.1% – 99.4%)		
Overall Agreement:	97.4 % (95% CI: 94.4% – 99.0%)		

pecimen positivity breakdown based on age of the patient:

Age	COVID-19 Antigen Rapid Test Device		
	Total #	Total Positive	Prevalence
<18 years	11	2	18.2%
6 to 21 years	52	9	17.3%
22 to 59 years	133	37	27.1%
≥60 years	34	6	17.6%

able below shows the positive results broken down by days since symptom onset:

Days Since Symptom Onset	Specimens Tested	RT-PCR Positive(+)	COVID-19 Antigen Rapid Test Device Positive(+)	PPA	95%CI
0	21	6	6	100.0%	61.0%-100.0%
1	38	17	17	100.0%	81.6%-100.0%
2	43	9	9	100.0%	70.1%-100.0%
3	25	7	7	100.0%	64.6%-100.0%
4	19	8	7	87.5%	52.9%-97.8%
5	12	2	2	100.0%	34.2%-100.0%
6	17	1	1	50.0%	9.4%-90.6%
7	4	1	1	100.0%	20.7%-100.0%
9	3	1	0	0.0%	0.0%-79.3%

e 2: With nasal Swab as a sample type

performance of the COVID-19 Antigen Rapid Test Device was established with 178 direct swabs collected and enrolled from individual symptomatic patients who were suspected of VID-19 (within 5 days from symptom onset). Multiple sites across the United States cipated in this study. The specimen were tested fresh by Point-of-Care operators with no istry experience, and FDA EUA RT-PCR assay for the detection of SARS-CoV-2 was ed as the comparator method for the study.

mary of the Performance of the COVID-19 Antigen Rapid Test Device Compared to RT-PCR

COVID-19 Antigen Rapid Test	RT-PCR		Total
	Positive	Negative	
Positive	60	6	66
Negative	5	113	118
Total	65	113	178
Positive Percent Agreement (PPA)	92.3% (95% CI: 83.2% – 96.7%)		
Negative Percent Agreement (NPA)	100.0% (95% CI: 96.7% – 100.0%)		
Overall Agreement:	97.2% (95% CI: 93.6% – 98.8%)		

Note:

Clinical studies in asymptomatic patients undergoing serial testing are ongoing to establish the clinical performance.

The performance of this test has not yet been clinically validated for use in patients without signs and symptoms of respiratory infection or for serial screening applications, and performance may differ in these populations.

Analytical Sensitivity (Limit of Detection):

The limit of detection was $2x10^{2}$ $TCID_{50}$/mL, and was determined using inactivated SARS-CoV-2 virus spiked into swabs.

Cross Reactivity and Microbial Interference:

There was no cross-reaction with the following organisms tested with the COVID-19 Antigen Rapid Test Device.

HCoV-HKU1	Influenza A (H5N1)	Coxsackie virus A16
HCoV-OC43	Influenza A (H7N9)	Norovirus
HCoV-NL63	Influenza A (H7N7)	Mumps virus
HCoV-229E	Influenza B Victoria lineage	*Legionella pneumophila*
Mouse virus	Influenza B Yamagata lineage	*Mycoplasma pneumoniae*
Streptococcus pneumoniae	Respiratory syncytial virus	*Chlamydia pneumoniae*
Epstein-Barr virus	Adenovirus	*Streptococcus pyogenes*
Bordetella parapertussis	Parainfluenza 1/2/3/4 virus	*Streptococcus agalactiae*
Bordetella pertussis	Haemophilus influenzae	Candida albicans
InfluenzaA (H1N1 [pdm09]	Human metapneumovirus	Group C *Streptococcus*
Influenza A (H3N2)	Rhinovirus	*Staphylococcus aureus*
Mycobacterium tuberculosis	Pooled human nasal wash – representative of normal respiratory microbial flora	

Interfering Substances

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the respiratory tract, were evaluated at the concentrations listed below. None of them were found to affect test performance of The COVID-19 Antigen Rapid Test Device.

Substance	Concentration	Substance	Concentration
3 OTC nasal sprays	10%	Guaiacol glyceryl ether	20 mg/ml
3 OTC mouthwashes	10%	Mucin	1%
3 OTC throat drops	10%	Mupirocin	250 μg/ml
4-acetamidophenol	10 mg/ml	Oxymetazoline	10 mg/ml
Acetylsalicylic acid	20 mg/ml	Phenylephrine	10 mg/ml
Albuterol	20 mg/ml	Phenylpropanolamine	20 mg/ml
Chlorpheniramine	5 mg/ml	Relenza® (zanamivir)	20 mg/ml
Dexamethasone	5 mg/ml	Rimantadine	500 ng/ml
Dextromethorphan	10 mg/ml	Tamiflu® (oseltamivir)	100 ng/ml
Diphenhydramine	5 mg/ml	Tobramycin	40 mg/ml
Doxylaminesuccinate	1 mg/ml	Triamcinolone	14 mg/ml
Fluticasone	5 mg/ml	Whole blood	4%

High-dose Hook Effect

The COVID-19 Antigen Rapid Test Device demonstrated that no hook effect at $1x10^{5.4}$ $TCID_{50}$/mL.

LITERATURE REFERENCES

1. Forni, D., Cagliani, R., Clerici, M. & Sironi, M. Molecular evolution of human coronavirus genomes. Trends Microbiol. 25, 35–48 (2017).
2. Hemo, N. L. et al. Close relative of human Middle East respiratory syndrome coronavirus in bat, South Africa. Emerg. Infect. Dis. 19, 1697–1699 (2013).

GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		Do not reuse

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