COV-S35

COVID-19 Antigen Rapid Test Device

INTENDED USE

The COVID-19 Antigen Rapid Test Device is an in vitro immunoassay. The assay is for the direct and qualitative detection of SARS-CoV-2 viral nucleoprotein antigens from saliva sample. This test is intended for professional use only.

PRINCIPLE

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

During testing, target antigens, if present in the saliva samples, will be released into the extraction buffer individually packed in the kit. Consequently, the extracted antigens will bind to anti-SARS-CoV-2 antibodies conjugated to colored particles. As the specimen migrates along the strip by capillary action and interacts with reagents on the membrane, the complex will be captured by the anti-SARS-CoV-2 antibodies at the test region. Excess colored particles are captured at the internal control zone.

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

MATERIALS

Materials Provided

- The test device
- Protector
- Tube with extraction buffer
- Package insert

Materials Required but Not provided

- Clock, timer or stopwatch

PRECAUTIONS

- For *in vitro* Diagnostic Use Only.
- DO NOT eat, drink, smoke, brush teeth, or chew gum for 30 minutes before collecting saliva.
- Caution should be taken when inserting sponge into the mouth in case of choking.
- DO NOT ingest.
- Read the Package Insert prior to use. Directions should be read and followed carefully.
- Do not use kit or components beyond the expiration date.
- 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 or eyes 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.

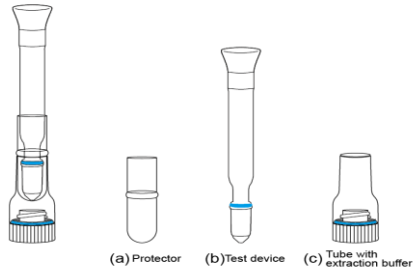
STORAGE AND STABILITY

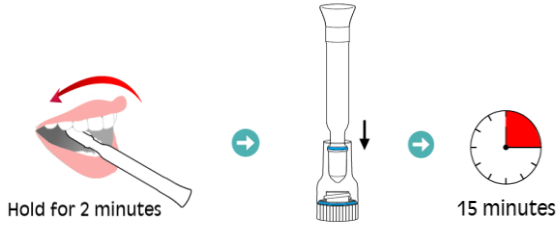
- Store The COVID-19 Antigen Rapid Test Device at 2~30℃when not in use.
- **DO NOT FREEZE**.
- Kit contents are stable until the expiration dates marked on their outer packaging and containers.

TEST PROCEDURE

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

1. Remove the test device from its packing. Label the device with the patient's identification. For the best results, the assay should be performed within two hours.
2. 1) Take the test device out of the tube with extraction buffer.
   2) Remove the protector.
3. Handle the test device into the mouth, hold for 2 minutes.
4. Place the test device vertically into the tube with extraction buffer.
5. Read the results at 15 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

Good laboratory practice suggests testing positive and negative external controls to ensure that the test reagents are working and that the test is correctly performed.

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.
4. Failure to follow the TEST PROCEDURE and RESULT INTERPRETATION may adversely affect test performance and/or invalidate the test result.
5. 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.
6. Negative results do not preclude SARS-CoV-2 infection and should be confirmed via molecular assay.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity (Limit of Detection):

The limit of detection was determined with a quantified SARS-CoV-2 virus and has been evaluated at $1.6x10^{1.4}TCID_{50}$/mL.

The limit of detection was also determined with recombinant SARS-CoV-2 nucleoprotein and has been evaluated at 40 pg/mL.

Clinical Evaluation:

Clinical evaluation was performed to compare the results obtained by COVID-19 Antigen Rapid Test and RT-PCR. The results were summarized below:

Table: COVID-19 Rapid Test vs. RT-PCR

		RT-PCR		Total
		Positive	Negative	
COVID-19 Antigen Rapid Test	Positive	18	2	20
	Negative	2	64	66
Total		20	66	86

Relative Sensitivity: 90.0 % (69.9% ~ 97.2%)*

Relative Specificity: 97.0 % (89.6% ~ 99.2%)*

Overall Agreement: 95.3 % (88.6% ~ 98.2%)*

*95% Confidence Interval

Cross Reactivity:

Cross reactivity with the following organisms has been studied. Samples positive for the following organisms were found negative when tested with the COVID-19 Antigen Rapid Test Device (Saliva).

InfluenzaA (H1N1)pdm09	HCoV-HKU1	Human rhinovirus 2, 14, 16
Influenza A (H3N2)	HCoV-OC43	Parainfluenza 1/2/3 virus
Influenza A (H5N1)	HCoV-NL63	Sendai virus
Influenza A (H7N7)	HCoV-229E	Herpes simplex virus 1
Influenza A (H7N9)	Human herpesvirus 2, 5	Herpes simplex virus 2
Influenza B Victoria lineage	Rubella virus	Mumps virus
Influenza B Yamagata lineage	Respiratory syncytial virus	Varicella-Zoster virus
Echovirus 2, 3, 6	Coxsackie virusA16	Adenovirus
Norovirus	Human metapneumovirus	Coxsackie virus A9, B5
Epstein-Barr virus	*Streptococcus pneumoniae*	Measles virus
Mycobacterium avium	*Aspergillus fumigatus*	*Burkholderia cepacia*
Histoplasma capsulatum	*Cryptococcus neoformans*	*Moraxella catarrhalis*
Mycobacterium tuberculosis	*Haemophilusinfluenzae*	*Bordetella pertussis*
Corynebacterium diphtheria	*Streptococcus salivarius*	*Mycobacterium intracellulare*
Neisseria meningitides	*Chlamydia pneumoniae*	*Streptococcus pyogenes*
Legionella pneumophila	*Streptococcus agalactiae*	Group C *Streptococcus*
Mycoplasma pneumoniae		

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 glycerol 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	25μg/ml
Acetylsalicylic acid	10 mg/mL	Phenylephrine	10 mg/mL
Albuterol	10 mg/mL	Phenylpropanolamine	1 mg/mL
Chlorpheniramine	5 mg/mL	Zanamivir	10 mg/mL
Dexamethasone	50 μg/ml	Adamantanamine	500 ng/mL
Dextromethorphan	10 μg/ml	Oseltamivir phosphate	10 mg/mL
Diphenhydramine	5 mg/mL	Tobramycin	10 mg/mL
Doxylamine	1 mg/mL	Triamcinolone	14 mg/mL
Flunisolide	25 μg/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. Ithete, 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		Contains sufficient for <n> tests
	Do not reuse	EC REP	Authorized representative in the European Community
CE	CE marking according to IVD Medical Devices Directive 98/79/EC		

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