COVID-19 Antigen Rapid Test Cassette (Oral Fluid)
Package Insert
REF: **COV-2C25B**

A rapid test for the qualitative detection of COVID-19 antigen in oral fluid.
For professional in vitro diagnostic use only.

INTENDED USE

The Rapid Response™ COVID-19 Antigen Rapid Test Cassette (Oral Fluid) is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 viral nucleoprotein antigens in Oral Fluid from individuals suspected of COVID-19 infection. This test is intended for professional use only.

INTRODUCTION

Coronavirus Disease 2019 (COVID-19) is an infectious disease caused by the recently discovered SARS-CoV-2 virus. The most common symptoms of COVID-19 are fever, dry cough and fatigue. Other symptoms may include sore throat, headache, muscle aches and pains, nausea, or difficulty breathing.
Older people and those with underlying medical problems like cardiovascular disease, chronic respiratory disease, diabetes and cancer are more likely to develop serious illness. The SARS-CoV-2 virus is transmitted primarily through direct, indirect or close contact with infected individuals through infected secretions such as respiratory droplets that are expelled while coughing, sneezing, talking or singing. Respiratory droplets that include virus can reach the mouse, nose or eyes of a susceptible person and can result in infection. Some data suggests that indirect transmission involving aerosol airborne particles or contaminated services may also be possible. the virus may be transmitted through airborne particles or on contaminated surfaces. Current epidemiological findings show that the incubation period can be 1 to 14 days and is most often 3 to 7 days.

PRINCIPLE

The Rapid Response™ COVID-19 Antigen Rapid Test Cassette (Oral Fluid) detects SARS-CoV-2 viral antigens through visual interpretation of color development. Antibodies specific to the Nucleocapsid (N) protein of SARS-CoV-2 are coated on the test line region on the membrane of the test cassette. A sample is added to the extraction reagent which is optimized to release the SARS-CoV-2 antigens from specimen. During testing, the extracted antigens from the specimen will react with the anti-SARS-CoV-2 antibodies that are coated onto the 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 to generate a coloured line.
The presence of a coloured line in the test region indicates a positive result for the SARS-CoV-2 viral antigens, while the absence of a line indicates a negative result. A colored line at the control region should always appear. It serves as a procedural control, indicating that the proper volume of specimen has been added and the test has performed properly.

MATERIALS

Materials Provided

- Test cassettes
- Collection tubes
- Package insert (IFU)
- Extraction Reagent
- Workstation

Materials Required but Not provided

- Clock, timer, or stopwatch

PRECAUTIONS

Please read all the information in this package insert before performing the test. Failure to follow instructions properly may decrease assay sensitivity or yield false results.
- For professional in vitro diagnostic use only.
- Do not use after the expiration date.
- The test should remain in the sealed pouch until ready to use. Do not use test cassette if pouch is damaged or open.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to the local regulations.
- Avoid using bloody samples.
- Wear gloves when handling the samples. Avoid touching the reagent membrane and sample well.

STORAGE AND STABILITY

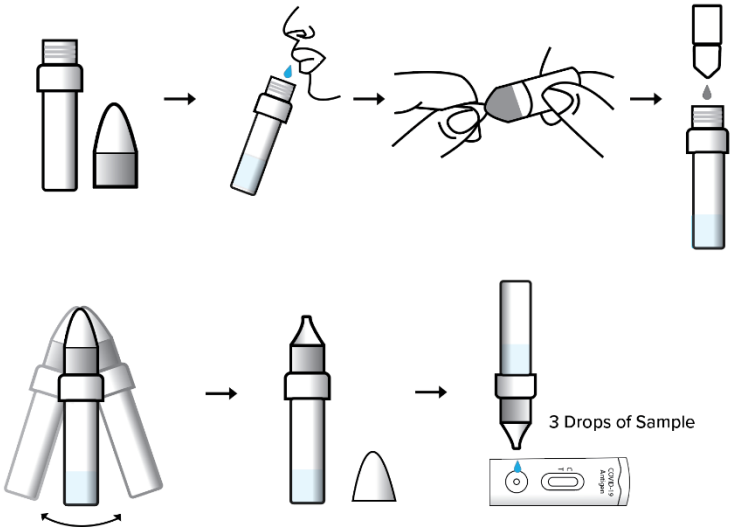
- Store the Rapid Response™ COVID-19 Antigen Rapid Test Cassette (Oral Fluid) at room temperature or refrigerated (2-30°C).**DO NOT FREEZE.**
- The test is stable until the expiration date printed on the sealed pouch. Do not use the test beyond the expiration date.
- The test must remain in the sealed pouch until use.

SPECIMEN COLLECTION AND PREPARATION

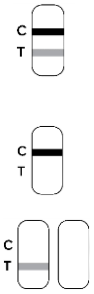
Use the provided collection tube to collect oral fluid. Unscrew the cap of the collection tube. Hold the collection tube close to the lips and let the oral fluid flow into the collection tube. The volume of oral fluid must be between the two black lines (approx. 150-300µl).

TEST PROCEDURE

Allow the test cassette, specimen and extraction buffer to equilibrate to room temperature (15-30°C) prior to testing.
1. Remove the test cassette from the sealed foil pouch and use it within one hour. For best results, perform the assay immediately after opening the foil pouch.
2. Place the collection tube with oral fluid in the workstation. Twist the tab to open the extraction reagent container and add all the extraction buffer (approx. 300µl) to the specimen collection tube.
3. Screw on the cap of the specimen collection tube and tighten so that it is fully sealed. Shake the specimen collection tube vigorously to mix the oral fluid and the extraction buffer.
4. Hold the specimen collection tube upright and open the cap onto the specimen collection tube. Invert the specimen collection tube and transfer 3 full drops of the extracted specimen (approximately 80 µL) to the specimen well (S) of the test cassette, then start the timer. Avoid trapping air bubbles in the specimen well (S). Read the result at 10 minutes. Do not interpret the result after 20 minutes.



RESULT INTERPRETATION



POSITIVE: * Two lines appear in the results region. One colored line should be in the control line region (C) and another colored line should be apparent in the test line region (T). A positive result indicates that SARS-CoV-2 was detected in the specimen.

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). A negative result indicates that SARS-CoV-2 antigen is not present in the specimen or is present below the detectable level of the test.

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 use of the test kit immediately and contact your distributor.

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of SARS-CoV-2 antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

QUALITY CONTROL

Internal Procedural Control: A procedural control is included in the test. The colored line appearing in the control line region (C) is considered an internal procedural control. It confirms adequate membrane wicking.
External Positive and Negative Controls: Control standards are not supplied with this kit. Good laboratory practice recommends testing positive and negative external controls to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

- The Rapid Response™ COVID-19 Antigen Rapid Test Cassette (Oral Fluid) is for professional in vitro diagnostic use only. The test should be used for the detection of COVID-19 Antigen in oral fluid. Neither the quantitative value nor the rate of increase in SARS-CoV-2 virus concentration can be determined by this qualitative test.
- The accuracy of the test depends on the quality of the oral fluid sample. False negatives may result from improper sample collection or storage.
- The Rapid Response™ COVID-19 Antigen Rapid Test Cassette (Oral Fluid) will only indicate the presence of SARS-CoV-2 in the specimen from both viable and non-viable SARS-CoV-2 coronavirus strains.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician before a definitive clinical diagnosis is made.
- A negative result obtained from this kit should be confirmed by PCR. A negative result may be obtained if the concentration of the SARS-CoV-2 virus present in the oral fluid is not adequate or is below the detectable level of the test.
- Excess mucus or blood in the oral fluid specimen may interfere with test performance and may yield a false positive result.
- A positive result for SARS-CoV-2 infection does not preclude an underlying co-infection with another pathogen, therefore the possibility of an underlying bacterial infection should be considered.
- 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.
- Positive results may be due to present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
- 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.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity (Limit of Detection):
The LOD for the Rapid Response™ Covid-19 Antigen Rapid Test Cassette (Oral Fluid) was established using limiting dilutions of a viral sample inactivated. The Estimated LOD is 1x 10^3 $TCID_{50}$/mL

Clinical Evaluation:
Clinical evaluation was performed to compare the results obtained by Rapid Response™ COVID-19 Antigen Rapid Test Cassette (Oral Fluid) and an RT-PCR comparator assay. The performance was evaluated by collecting two specimens from each donor. One was tested with PCR comparator and the other was tested with the Rapid Test Cassette (Oral Fluid). The study included 40 positive specimens and 324 negative specimens. The oral fluid specimens were considered positive if PCR indicated a positive result.

Method		RT-PCR		Total Results
Rapid Response™ Covid-19 Antigen Rapid Test Cassette	Results	Positive	Negative	
	Positive	38	0	38
	Negative	2	324	326
Total Results		40	324	364

Relative Sensitivity: 95.0% (83.1%-98.4%)*
Relative Specificity: 99.9% (99.1%-100.0%)*
Relative accuracy: 99.5% (98.0%-99.9%)*
* 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 Rapid Response™ COVID-19 Antigen Rapid Test Cassette.

Human coronavirus 229E	Adenovirus (e.g. C1 Ad. 71)	Respiratory syncytial virus-Type A
Human coronavirus OC43	Enterovirus (e.g. EV68)	Bordetella pertussis
Human coronavirus NL63	Influenza A (H3N2)	Haemophilus influenzae
MERS-coronavirus	Influenza A H1N1	*Legionella pneumophila*
Staphylococcus aureus	Influenza B (Florida/02/06)	*Mycoplasma pneumoniae*
Neisseria meningitides	Parainfluenza virus 1/2/3/4	*Pneumocystis jirovecii (PJP)-S.cerevisiae Recombinant*
Streptococcus sp. group A	Parainfluenza Virus Type4a	*Pseudomonas aeruginosa*
Streptococcus sp. group B	Mumps virus	*Streptococcus pneumoniae*
Streptococcus sp. group C	Rhinovirus	Streptococcus pyogenes
Human Metapneumovirus (hMPV)	Haemophilus parainfluenzae	*Streptococcus salivarius*
Candida albicans	Staphylococcus epidermis	*Mycobacterium tuberculosis*

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 Rapid Response™ COVID-19 Antigen Rapid Test Cassette (Oral Fluid).

Ambroxol Hydrochloride Tablets (7.5 mg/mL)	Mometasone furoate nasal spray (0.05% g/g)	Nin Jiom Pei Pa Kao cough syrup
Dextromethorphan Hydrobromide Ora Solution (1.5 mg/ml)	Mucosolvan Ambroxol Hydrochloride Oral Solution	Nasal cleansing solution, NaCl (5 g/L)
Hyland's 4 Kids Cold Cough Liquid Safe Natural Relief	Durham's Canker-Rid	Listerine mouthwash
Scope mouthwash	Nasal antibioitic (Mupirocin Ointment)	Oxymetazoline Hydrochloride Spray
Beclomethasone Dipropionate Nasal Aerosol	Triamcinolone Acetonide Nasal Spray	Azelastine Hydrochloride Nasal Spray
Fluticasone Propionate Nasal Spray	Physiological Seawater Nasal Spray	Tobramycin Eye Drops
Whole blood (4%)	Mucin (0.05%)	

High Dose Hook Effect
No high dose hook effect was observed when tested with up to a concentration of 1 x 10^5 $TCID_{50}$/mL of heat inactivated SARS-CoV-2 virus with the Rapid Response™ COVID-19 Rapid Test Cassette (Oral Fluid).

LITERATURE REFERENCES

1. Forni, D., Cagliani, R., Clerici, M. & Sironi, M. Molecular evolution of human coronavirus genomes. Trends Microbiol. 25, 35–48 (2017).
2. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. *Trends Microbiol.* 2016;24:490-502.
3. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. *Adv. Virus. Res.* 2011;81:85-164.
4. World Health Organization. (2020). Transmissions of SARS-CoV-2: Implications for infection prevention precautions, July 9 2020. Scientific Brief. World Health Organization.

GLOSSARY OF SYMBOLS

Consult Instructions for use	Tests per kit	EC REP	Authorized Representative
For in vitro diagnostic use only	Use by		Do not reuse
Store between 2-30°C	Lot Number	**REF**	Catalog #
Do not use if package is damaged			

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