BNG SARS-CoV-2 Antigen Rapid Test

(Saliva)

Package Insert

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

[INTENDED USE]

The COVID-19 Antigen Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of COVID-19 antigen in Saliva. The identification is based on the monoclonal antibodies specific for the Nucleocapsid（N）protein and spike（S）protein of SARS-CoV-2. It is intended to aid in the rapid differential diagnosis of COVID-19 infections.

[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. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. 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 Cassette (Saliva) is a qualitative, lateral flow immunoassay for the detection of the N protein and S protein of SARS-CoV-2 in saliva. In this test, antibody specific to the N protein and S protein of SARS-CoV-2 is separately coated on the test line regions of the test cassette. During testing, the extracted specimen reacts with the antibody to N protein and S protein of SARS-CoV-2 that are coated onto particles. The mixture migrates up the membrane to react with the antibody to N protein and S protein of SARS-CoV-2 on the membrane and generate one colored line in the test regions. The presence of this colored line of the test regions indicates a positive result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

[REAGENTS]

The test cassette contains anti- coronavirus 2019-nCoV Nucleocapsid protein particles , anti-coronavirus 2019-nCoV spike protein particles and anti- coronavirus 2019-nCoV Nucleocapsid protein , anti- coronavirus 2019-nCoV spike protein coated on the membrane.

[PRECAUTIONS]

Please read all the information in this package insert before performing the test.

1. For professional in vitro diagnostic use only. Do not use after the expiration date.
2. The test should remain in the sealed pouch until ready to use.
3. All specimens should be considered potentially hazardous and handled in the same manner as an infection agent.
4. The used test should be discarded according to the local regulations.
5. Avoid using bloody samples.
6. Wear gloves when handling the samples, avoid touching the reagent membrane and sample well.

[STORAGE AND STABILITY]

Store as packaged 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. Do not use beyond the expiration date.

[SPECIMEN COLLECTION AND PREPARATION]

Use the collection tube and saliva collector to collect saliva. Unscrew the cap of the collection tube. Put the collection tube (inserted saliva collector) close to lips and let the saliva flow into the collection tube. The volume of saliva needs to be 0,5 ml line of the collection tube. If the saliva specimen exceeds the upper scale (0,5ml) when collecting, use a dropper to suck it out make the sample at the 0,5 ml line. For best results please do not eat, drink, smoke, vape or brush teeth within 30 minutes of providing your sample. Do not use mouthwash 2 hours before collecting samples. Ideally, it is best to collect saliva samples first thing in the morning.

[MATERIALS]

Materials provided

Test cassette, Extraction reagent, Dropper, Collection tube, Saliva collector, Tube package

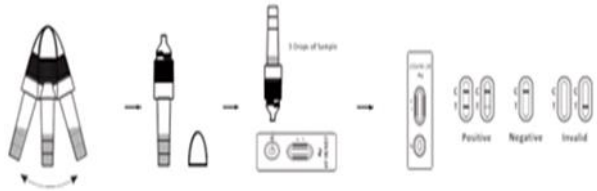
Materials required but not provided

Timer

[DIRECTIONS FOR USE]

Allow the test, specimen, 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. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2. Place the collection tube with saliva using saliva collector. Remove the saliva apparatus from the collector tube and transfer 0.5ml of saliva with dropper to the extraction tube.
3. Screw on and tighten the cap onto the extraction tube. Then shake the extraction tube vigorously to mix the saliva and the extraction buffer.
4. Hold the extraction 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 80µL) 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.



[INTERPRETATION OF RESULTS]

(Please refer to the illustration above)

POSITIVE:* Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T). A positive result indicates that COVID-19 was detected in the specimen.

*NOTE: The intensity of the color in the test line region (T) will vary depending on the concentration of COVID-19 Antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

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 COVID-19 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 using the test kit immediately and contact your local distributor.

[QUALITY CONTROL]

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms adequate membrane wicking. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

[LIMITATIONS]

1. The COVID-19 Antigen Rapid Test Cassette (Saliva) is for professional in vitro diagnostic use only. The test should be used for the detection of COVID-19 Antigen in Saliva. Neither the quantitative value nor the rate of increase in SARS-CoV-2 virus concentration can be determined by this qualitative test.
2. The accuracy of the test depends on the quality of the saliva sample. False negatives may result from improper sample collection or storage.
3. The COVID-19 Antigen Rapid Test Cassette (Saliva)will only indicate the presence of SARS-CoV-2 in the specimen from both viable and non-viable SARS-CoV-2 coronavirus strains.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. 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 saliva is not adequate or is below the detectable level of the test.
6. Excess blood or mucus on the saliva specimen may interfere with test performance and may yield a false positive result.
7. A positive result for COVID-19 does not preclude an underlying co-infection with another pathogen, therefore the possibility of an underlying bacterial infection should be considered.
8. 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.
9. Positive results may be due to present infection with non-SARS-CoV-2 coronavirus strains,such as coronavirus HKU1, NL63, OC43, or 229E.
10. 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 CHARACTERİSTICS]

Sensitivity, Specificity, Accuracy

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

Method		RT-PCR		Total Results
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% (95%CI*:83.1%-98.4%)
* Relative Specificity: ＞99.9% (95%CI*:99.1%-100.0%)
* Relative accuracy: 99.5% (95%CI*:98.0%-99.9%)*
* Confidence Intervals

Detection Limit

The LOD for the COVID-19 Antigen Rapid Test Cassette(Saliva) was established using limiting dilutions of a viral sample inactivated. The material(ZeptoMetrix, 0810587CFHI) was supplied at a concentration of 1.15 x 107TCID50/mL. The Estimated LOD is 1000 TCID50/mL.

Cross Reactivity

The COVID-19 Antigen Rapid Test Cassette (Saliva) has been tested for Influenza A virus, Influenza B virus, Adenovirus, Coxsackie virus, Parainfluenza Virus Type1, Parainfluenza Virus Type2, Parainfluenza Virus Type3, Parainfluenza Virus Type4a, Enterovirus, Mumps virus, Respiratory syncytial virus, Rhinovirus, Bordetella pertussis, Haemophilus parainfluenzae, Staphylococcus aureus, Streptococcus agalactiae, Neisseria meningitides, Streptococcus sp. group A, Streptococcus sp. group B, Streptococcus sp. group C, Candida albicans, Human Metapneumovirus (hMPV),Bordetella pertussis, Legionella pneumophila, Mycobacterium tuberculosis, Mycoplasma pneumoniae, Pneumocystis jirovecii(PJP)-S cerevisiae Recombinant, Pseudomonas aeruginosa, Staphylococcus epidermis, Streptococcus pneumoniae, Streptococcus salivarius, Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, MERS-coronavirus positive specimens.The results showed no cross reactivity.

[BIBLIOGRAPHY]

1. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011;81:85-164.
2. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019;17:181-192.
3. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. TrendsMicrobiol 2016;24:490-502.

	Consult instruction for use		Test per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 2-30°C	LOT	Lot Number	REF	#Catalog
	Do not use if package id damaged				

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