Saliva SARS-Cov-2 (2019-nCoV)

Antigen Combined Test Kit

(Nanocarbon Assay)

Instructions

PRODUCT NAME

Saliva SARS-Cov-2(2019-nCoV)Antigen Combined Test Kit（Nanocarbon Assay）

CATALOG NUMBER

NBMLRS-XG-S1

PACKAGE SPECIFICATION

20 Tests / Box

INTENDED USE

Saliva SARS-Cov-2(2019-nCoV)Antigen Combined Test Kit（Nanocarbon Assay）is a lateral flow, one-step immunoassay for the qualitative detection of N/ S antigen in Saliva sample. This product is used to obtain a visual, qualitative results and is intended for professional use.

This assay provides only a preliminary analytical test result. A more specific alternate method must be used in order to obtain a confirmed analytical result. Virus nucleic acid test is the preferred confirmatory method.

DETECTTION PRINCIPLES

The One Step SARS-CoV-2 N/ S antigen Test Device is a rapid chromatographic immunoassay based on the principle of sandwich antibody and antigen binding.

During testing, SARS-CoV-2 N/ S antigen, if the Virus antigens present in the saliva specimen it will bind to the antibody conjugates to form a complex. And migrates upward by capillary. The complex will then be captured by the immobilized antibody coated at the Test line region on the NC membrane. A visible black line will show up in the test line region. The black line will not form in the test line region if there is no virus antigen in the sample.

A virus antigen-positive saliva specimen will generate a colored line in the test line region because of antigen binding, while a virus antigen-negative saliva specimen or a specimen containing a very low concentration will not generate a colored line in the test line region.

To serve as a procedural control, a colored line will always appear at the control line region (C line), indicating that proper volume of specimen has been added and membrane wicking has occurred.

MAJOR COMPONENTS

Component Name	Major Biochemical Composition
Saliva SARS-Cov-2(2019-nCoV) Antigen Combined Test Kit	It consists of strips, plastic cards, desiccants and aluminum foil bags. Strips consist of plastic substrates, colloidal Nanocarbon pads, cellulose films, loading pads, and absorbent pads. Colloid Nanocarbon pads are pre-coated with Nanocarbon-labeled anti-N and S antigen monoclonal antibodies, and the detection line of nitrocellulose. The QC line is goat anti-mouse IgG antibody.
Instruction	Printed text

STORAGE CONDITIONS AND EXPIRATION DATE

The product should be stored at 2℃-30℃ in a dry place and avoid light; it expires in 12 months from the date of its production and must not be frozen.

The product should be used in an hour after the aluminum foil bag is torn; if the aluminum foil bag is torn in an environment with high humidity, it should be immediately used. Do not use beyond the expiration date.

REQUIREMENTS FOR SAMPLES

Saliva specimens may be stored at 2-8℃ for up to 48 hours. For long-term storage, specimens may be frozen and stored below -20℃. Frozen specimens should be thawed and mixed before testing.

SAMPLES COLLECTING METHOD

Put tongue on upper jaw and bow head to make saliva secrete naturally into a disposable plastic cup, and collect at least 2ml saliva.

TESTING METHOD

Saliva specimen should be brought to room temperature (20-30℃) prior to testing. Do not open pouches until ready to perform the testing.

1. Remove the test cassette from its package and place it on a clean and level surface.
2. Insert the suction rod vertically into the disposable plastic cup containing saliva (at least 2ml). Require the suction rod to be immersed in saliva for at least 2 minutes. During the period, the suction rod can be changed slightly to suck up the liquid. When the liquid appears in the observation window, take out the test and place it on a clean and flat table, and start the timer.
3. Read result after 15 minute. Do not read result after 30 minutes.

EXPLANATION OF TEST RESULTS

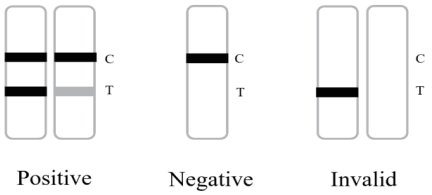
1.Result Evaluation

1.1. Positive: Two lines appear. One black line should be in the control region (C), and another apparent black line should be in the test region (T). This positive result indicates that there are SARS-CoV-2 N/S antigens present in the saliva specimen.

1.2. Negative: One black line appears in the control region (C). No line appears in the test region (T). This negative result indicates that there are no SARS-CoV-2 N/ S antigens present in the saliva specimen or the antigen concentration is too low.

1.3. Invalid Control line fails to appear. Insufficient specimen volume ,incorrect procedure or technical error are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test device. If the problem persists, discontinue using the lot immediately and contact your local distributor.

2.The shade of color in the test line region (T) will vary, but it should always be considered as positive whenever there is even a faint black line.



LIMITATIONS OF THE TEST METHOD

1. The test device provides only a preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Virus nucleic acid test is the preferred confirmatory method.
2. The device is a qualitative screening assay and cannot determine either the concentration of the antigen in the saliva or the level of the virus.
3. It is possible that technical or procedural errors, as well as other interfering substances in the saliva specimen may cause erroneous results.
4. Adulterants, such as bleach and/or alum, in saliva specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another saliva specimen.
5. A Positive Result indicates presence of the antigen but does not indicate level of the virus in saliva.
6. A Negative Result may not necessarily indicate virus-free saliva. Negative results can be obtained when virus is present but below the cutoff level of the Test.

NOTES

1. For in vitro diagnostic use only. For professional use only.
2. Do not use after the expiration date.
3. The test Cassette should remain in the sealed pouch and until use.
4. Saliva specimen may be potentially infectious. Proper handling and disposal measures should be adopted.
5. The used test Cassette should be discarded according to federal, state and local regulations.

PERFORMANCE INDICATOR

1. Lower detection limit： Test the in-house reference materials, S1 is positive for SARS-CoV-2 N antigen, negative for S antigen; S2 is positive for SARS-CoV-2 S antigen, negative for N antigen; S3 is negative for SARS-CoV-2 N/S antigen; and S4 is positive for SARS-CoV-2 N/S antigen; with a coincidence rate of 100%.
2. Positive coincidence rate: Test in-house positive reference material S4, and the results are all positive for SARS-CoV-2 N/S antigen, with a coincidence rate of 100%.
3. Negative coincidence rate: Test in-house negative reference material S3, and the results are all negative for SARS-CoV-2 N/S antigen, with a coincidence rate of 100%.
4. Repeatability: Test in-house reference material S1/S2/S4, 10 times each, the results are all positive, with a coincidence rate of 100%.

5. Analytical specificity:

5.1 Cross reaction: This product will not cross react with positive samples of parainfluenza virus, influenza A virus antibody, influenza B virus, chlamydia pneumoniae, mycoplasma pneumoniae, adenovirus, respiratory syncytial virus, hepatitis B surface, hepatitis C virus, Treponema pallidum, human immunodeficiency virus, Epstein-Barr virus, measles virus, cytomegalovirus, enterovirus type 71, mumps virus, varicella-zoster virus.

5.2 Interferents: Histamine hydrochloride, α-interferon, zanamivir, ribavirin, oseltamivir, peramivir, lopinavir, ritonavir, abidor, levofloxacin, azithromycin, ceftriaxone Pine, meropenem, tobramycin have no effect on the test results.

6. Hook effect: Within the titer range of clinically positive samples of novel coronavirus antigen, there is no hook effect in the test results.
7. The precision test is conducted by different test personnel at different time with this kit, and the results comply with the requirements of product performance.
8. For virus infection samples from different regions, the lowest limit of detection and detection repeatability of the reagent comply with the requirements.

Clinical Report

RapideX Saliva™ One Step COVID-19 Antigen Test Performance within 5 days of symptom onset against the Reference RT-PCR Assay (N=180).

RapideX Saliva™ One Step COVID-19 Antigen Test	Reference RT-PCR Assay		
	Positive	Negative	Total
Positive	116	0	116
Negative	14	50	64
Total	130	50	180
Positive Agreement: 116/130		89.2% (95% CI: 82.6% - 94.0%)	
Negative Agreement: 50/50		100% (95% CI: 92.9% - 100%)	

COMPANY INFORMATION

Symbol			
REF	Reference	IVD	In Vitro Diagnosis
LOT	Batch Code		Read the instructions before use
	Contains enough for <N> tests		Do not reuse Use only once
	Reserve:2-30℃（35.6-86°F）		Maker
	Date of Expiry		Danger
EC REP	European authority certification	CE	CE Symbol

EC	REP