SARS-CoV-2 Antigen Rapid Test Kit (Anterior Nasal)

Detection kit for SARS-CoV-2 antigen in Nasal swab from human

(Packing Specification:20 Tests/box; 5Test/box; 1Test/box)

IVD CE

Cat.No.3021912

CE

IVD

SARS CoV-2 Antigen Anterior Nasal Rapid Detection Kit Instructions for use

A rapid test for the qualitative detection of antigens to the novel coronavirus SARS-CoV-2 in human nasal cavity.
For professional in vitro diagnostic use only.

PACKING SPECIFICATIONS

20 Tests/Packung 5 Tests/Packung 1 Test/Packung

INTENDED USE

The SARS-CoV-2 Antigen Rapid Test Kit (Anterior Nasal Check) is a rapid chromatographic immunoassay for the qualitative detection of novel coronavirus SARS-CoV-2 in human nasal cavity.

PRINCIPLE

TheSARS-CoV-2 Antigen Rapid Test Kit (Anterior Nasal Check) is for detection of the Nucleocapsid (N protein) of the SARS-CoV-2 antigens. anti-SARS-CoV-2 monoclonal antibodies are coated in the test line and conjugated with the colloidal gold. During testing, the specimen reacts with the anti-SARS-CoV-2 antibodies conjugate in the test strip. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with another Anti-SARS-CoV-2 monoclonal antibodies in the test region. The complex is captured and forming a colored line in the Test line region. The SARS-CoV-2 Antigen Rapid Test Kit (Anterior Nasal Check) contains anti-SARS-CoV-2 monoclonal antibodies conjugated particles and another anti-SARS-CoV-2 monoclonal antibodies are coated in the test line regions.

PRECAUTIONS

- For in vitro diagnostic use only. Do not use after expiration date.
- The Test strip should remain in the sealed pouch until use.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used Test Strip should be discarded according to national, state and local regulations.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

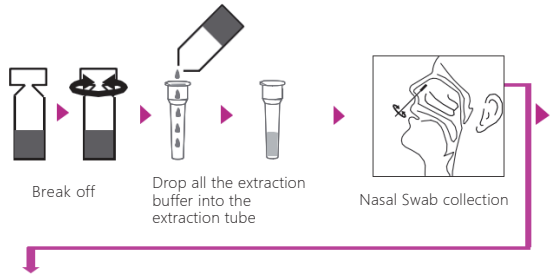
The kit can be stored at room temperature or refrigerated (2-30°C). The Test Strip is stable through the expiration date printed on the sealed pouch. The Test Strip must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date. The stability of the kit under these storage conditions is 18 months

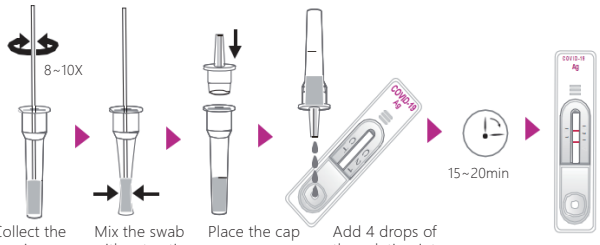
COMPONENTS

Materials Provided
1) Foil pouches, with test cassettes and desiccants
2) Extraction buffer tubes
3) Sterile swabs and specimen collection tubes
4) Specimen bags
5) Instruction for use
Materials Required But Not Provided
1) Specimen collection container
2) Timer

SPECIMEN COLLECTION AND PREPARATION

The SARS-CoV-2 Antigen Rapid Test Kit (Anterior Nasal Check) can be performed using specimen from nasal cavity.





- Take out an assay buffer tube and break off the head. Turn around and extrude all the buffer (approx. 0.5mL) into a sample collection tube. Insert the head of a sterile swab into one side of the deep nasal cavity.
- Gently rotate swab against wall of nasal cavity for 8-10 times. Avoid to break the wall or the turbinate of the nasal cavity. Then, take it out and repeat the collection from the other side nasal cavity. Make the swab wet as much as possible.
- Insert the swab into the sample collection tube. Rotate the swab and extrude the head of the swab, to make the specimen resolved in the assay buffer sufficiently.
- Remove the swab and add the tip onto the specimen collection tube. Use this prepared specimen in the assay.

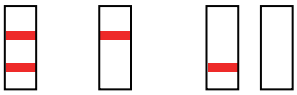
The assay should be performed immediately in 2 hours after the specimen preparation. If the assay could not be carried immediately, the prepared specimen should be kept no more than 24 hours at 2-8°C or 7 days at -20°C. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly for more than two times.
If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

TEST PROCEDURE

Allow the test device, specimen, buffer, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and horizontal surface. Reverse the specimen collection tube, extrude 3 drops of the prepared specimen into the specimen well (S) of the test cassette and start the timer.
3. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret the result after 15 minutes.

INTERPRETATION OF RESULTS



Positive Negative Invalid

- **Positive (+):** Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the T line region.
  *NOTE: The intensity of the color in the test line regions may vary depending on the concentration of SARS-CoV-2 present in the specimen. Therefore, any shade of color in the test line region should be considered positiveand recorded as such.
- **Negative (-):** One colored line appears in the control line region (C). No line appears in the T line region.
- **Invalid:** Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control

SARS-CoV-2 Antigen Rapid Test Kit (Anterior Nasal)

IVD CE

Detection kit for SARS-CoV-2 antigen in Nasal and oropharyngeal swab from human

(Packing Specification:20 Tests/box; 5Test/box; 1Test/box

Cat.No.3021912

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

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

LIMITATIONS

1. The SARS-CoV-2 Antigen Rapid Test Kit (Anterior Nasal Check) (COVID-19 Ag) is for in vitro diagnostic use only. This test should be used for the detection of SARS-CoV-2 antigens in specimen collected from the patient's nasal cavity.
2. The SARS-CoV-2 Antigen Rapid Test Kit (Anterior Nasal Check) (COVID-19 Ag) will only indicate the presence to SARS-CoV-2 in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infections.
3. Results from immunosuppressed patients should be interpreted with caution.
4. If the symptom persists, while the result from COVID-19 Rapid Test is negative or non-reactive result, it is recommended to re-sample the patient few days late or test with an alternative test device such as PCR.
5. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
6. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of COVID-19 infection.
7. The potential impacts of vaccines, antiviral therapeutics, antibiotics, chemotherapeutic or immunosuppressant drugs have not been evaluated in the test.
8. Due to inherent differences between methodologies, it is highly recommended that, prior to switching from one technology to the next, method correlation studies are undertaken to qualify technology differences. One hundred percent agreement between the results should not be expected due to differences between technologies.
9. Performance has only been established with the specimen types listed in the Intended Use. Other specimen types have not been evaluated and should not be used with this assay.

PERFORMANCE CHARACTERISTICS

1. Sensitivity, Specificity and Accuracy
The SARS-CoV-2 Antigen Rapid Test Kit (Anterior Nasal Check) (COVID-19 Ag) has been compared with a commercial gold standard reagent (PCR). The result showed the relative sensitivity and specificity (CT≤27)

Method		Gold standard reagent (PCR)		Total Results
SARS-CoV-2 Antigen Rapid Test (COVID-19 Ag)	Results	Positive	Negative	
	Positive	157	2	159
	Negative	4	228	232
Total Results		161	230	391

Relative Sensitivity: 97.5 %, (95% CI 93.76% to 99.32%)
Relative Specificity: 99.1%, (95% CI 96.89% to 99.89%)
Accuracy: 98.47% (95%CI 96.69% to 99.43%)
2. Limit of Detection (LOD)
The limit of detection of the SARS-CoV-2 Antigen Rapid Test Kit (Anterior Nasal Check) (COVID-19 Ag) has been studied. The LOD of the test to the SARS-CoV-2 N protein is around 0.2-0.5ng/mL. The LOD of the test to the SARS-CoV-2 virus (inactivated) is about 2-5X10^2 $TCID_{50}$/mL

Concentration	Positive/Result	Agreement Rate
0.5ng/mL N protein	100/100	100%
5X10^2 $TCID_{50}$/mL	100/100	100%

3. Cross-reactivity:
The SARS-CoV-2 Antigen Rapid Test Kit (Anterior Nasal Check) is associated with a panel of proteins of other human coronavirus recombinant antigens. The results showed in below sheet.

Substance	Concentration	Result
SARS-CoV-2 N protein	0.001μg/mL	positive
SARS-CoV N protein	1μg/mL	negative
MERS-CoV N protein	1μg/mL	negative
HCoV-NL63 N protein	1μg/mL	negative
HCoV-229E N protein	1μg/mL	negative
HCoV-HKU1 N protein	1μg/mL	negative
HCoV-OC43 N protein	1μg/mL	negative

4. Interfering Substances:
The following compoundsand other respiratory symptoms relative virus have been tested using theSARS-CoV-2 Antigen Rapid Test Kit (Anterior Nasal Check) and no interference was observed.

substance	concentration	result
alpha-interferon	3millionIU	No interference
Purified Mucin	1000ng/mL	No interference
Parainfluenza virus	1X$10^5$$TCID_{50}$/mL	negative
Influenza A virus	1X$10^5$$TCID_{50}$/mL	negative
Influenza B virus	1X$10^5$$TCID_{50}$/mL	negative
Chlamydia pneumoniae	1X$10^5$$TCID_{50}$/mL	negative
Adenovirus	1X$10^5$$TCID_{50}$/mL	negative
Mycoplasma pneumoniae	1X$10^5$$TCID_{50}$/mL	negative
Respiratory syncytial virus	1X$10^5$$TCID_{50}$/mL	negative

PRECISION

Intra-Assay
Within-run precision has been determined by using 15 replicates of two specimens: a negative, and an N protein (1ng/ml) as positive. The specimens were correctly identified >99% of the time.
Inter-Assay
Between-run precision has been determined by 15 independent assays on the same two specimens: a negative, an N protein (1mg/ml) as positive. Three different lots of the SARS-CoV-2 Antigen Rapid Test Kit (Anterior Nasal Check) have been tested using these specimens. The specimens were correctly identified >99% of the time.

CAUTIONS

1.For in-vitro diagnostic use only.
2.Must not use kit beyond the expiration date.
3.Do not mix components from kits with different lot number.
4.Avoid microbial contamination of reagents.
5.Use the test as soon as possible after opening to protect it from moisture.

INSTRUCTION APPROVAL AND REVISION DATE

Approval Date: 2021-01-16
Revision Date: 2021-01-16
Date of Issue: 2021-01-16

INDEX OF SYMBOLS

	Consult instructions for use	30°C 2°C	Store between 2-30°C		Use by
IVD	For in vitro diagnostic use only		Do not reuse	LOT	Lot Number
	Manufacturer	Σ	Tests per kit	REF	Catalog No
EC REP	European union authorized representative		Keep dry		Don't use the product when the package is damaged
	Biological risks	CE	The product meets the basic requirements of European in vitro. diagnostic medical devices directive 98/79/EC		

Zhejiang Anji Saianfu Biotech Co.,Ltd.
Add: 2nd Floor, No.3 Factory, No. 489 Wen Yun Road, TangPu Industrial Park, Dipu Subdistrict, AnJi County, 313303 HuZhou City, ZheJiang Province P.R. China
Tel : +86-572-5121502
Fax : +86-572-5068177
E-mail : sales@seinofy.com

CE EC REP
Brand-New Trading GmbH
Mondseestrasse 28/6 5310 Mondsee, Austria
+43 676 3500180