Sienna™

COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab)

Instruction for use

Ref: 102241

A rapid test for the qualitative detection of Novel Coronavirus SARS-CoV-2 antigen in Nasopharyngeal swab.

CE

For professional in vitro diagnostic use only

Store at 2°C – 30°C (36°F – 86°F)

CONTENT

1. INTENDED USE

The COVID-19 Antigen Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of COVID-19 antigen in Nasopharyngeal swab. The identification is based on the monoclonal antibodies specific for the Nucleocapsid protein of SARS-CoV-2. It is intended to aid in the rapid diagnosis of COVID-19 infections.

1.1. Abbreviations

SARS-CoV-2: novel coronavirus

COVID-19: novel coronavirus pneumonia

1.2. Summary

The new coronavirus belongs to the coronavirus of the genus β. It has an envelope and the particles are round or elliptical. They are often polymorphic and have a diameter of 60-140 nm. Its genetic characteristics are significantly different from SARS-CoV and MERS-CoV. Current research shows that the homology with bat SARS-like corona virus (bat-SL-CoVZC45) is more than 85%. When isolated and cultured in vitro, the new coronavirus can be found in human respiratory epithelial cells in about 96 hours, while it takes about 6 days to separate and culture in VeroE6 and Huh-7 cell lines.

The new coronavirus (SARS-COV-2) antigen detection method can effectively reduce the false negatives of RT- PCR and false positives of antibody detection methods. The diagnosis is fast, accurate and requires low equipment and personnel, suitable for rapid investigation of suspected cases of novel coronavirus infection on a large scale. The rapid investigation of suspected cases is effective during outbreaks and also can be used as a supplementary test for nucleic acid testing to avoid the risk of new transmission caused by the discharge of false negative patients.

2. PRINCIPLE

The COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) is a qualitative, lateral flow immunoassay for the detection of the N protein of SARS-CoV-2 in Nasopharyngeal swab. In this test, antibody specific to the N 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 of SARS-CoV-2 that are coated onto particles. The mixture migrates up the membrane to react with the antibody to N 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.

3. REAGENTS

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

4. PRECAUTIONS

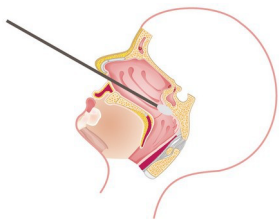
1. For professional in vitro diagnostic use only.
2. Follow the instructions for use carefully. Reliability of assay results cannot be guaranteed if there is any deviation from the instructions in this instruction for use.
3. The test should remain in the sealed pouch until ready to use.
4. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agents.
5. Avoid using bloody samples.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection before testing.
7. The used tests, specimens and potentially contaminated material should be discarded according to the local regulations.
8. Humidity and temperature can adversely affect results.
9. Do not store this kit in frozen condition.
10. Do not use the product if package is damaged.
11. Do not use the product after expiration date.
12. Do not re-use the product.
13. Use only the extraction solution provided with the kit.
14. Read and interpret the results at 10 minutes, do not interpret the results after 20 minutes.
15. Do not eat, drink or smoke in the area where the specimens or kits are handled.

5. STORAGE AND STABILITY

Store as packaged at room temperature or refrigerated 2°C – 30°C (36°F – 86°F). 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.

6. SPECIMEN COLLECTION AND PREPARATION

Insert swab through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. Swab should reach depth equal to distance from nostrils to outer opening of the ear. Gently rub and roll the swab. Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the swab is saturated with fluid from the first collection. If a deviated septum or blockage create difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.



Please use as soon as possible after taking samples.

7. MATERIALS

7.1. Material Provided

Item number	Content	Quantity
1	Instruction for use	1 piece
2	Individually Pouched Test Cassettes	25 cassettes
3	Extraction Buffer (NaCl + Casein Sodium + Tris + Proclin 300)	25 tubes
4	Sterile Swabs	25 pieces
5	Workstation	1 piece

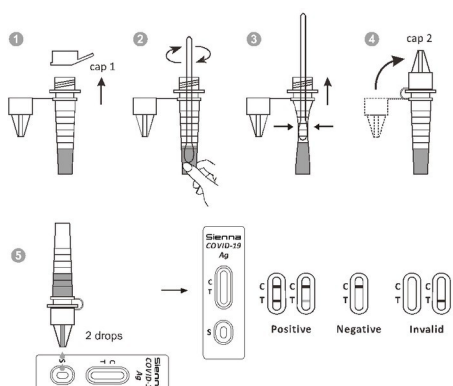
7.2. Materials required but not provided

- Timer
- Gloves

8. DIRECTIONS FOR USE

Allow the test cassette, specimen, supporting buffer to equilibrate to room temperature 15°C – 30°C (59°F – 86°F) 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 extraction buffer in the workstation. Open the cap 1 (See illustration 1) and place the swab specimen in the extraction buffer. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab. (See illustration 2).
3. Remove the swab while squeezing the swab head against the inside of the extraction buffer as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol (See illustration 3).
4. Tighten cap 2 (See illustration 4), place the test cassette on a clean and level surface.
5. Add 2 drops of the solution to the sample well (See illustration 5) and then start the timer. Read the result at 10 minutes. Do not interpret the result after 20 minutes.



9. INTERPRETATION OF THE RESULTS

9.1	**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.	
9.2	**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.	
9.3	**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 the manufacturer or your supplier.	

10. 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.

11. LIMITATIONS

1. This device is for professional in vitro diagnostic use only.
2. This device is only used for testing human nasopharyngeal swab specimens.
3. Neither the quantitative value nor the rate of increase in SAR-CoV-2 virus concentration can be determined by this qualitative test.
4. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
5. The COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab)will only indicate the presence of SARS- CoV-2 in the specimen from both viable and non-viable SARS-CoV-2 coronavirusstrains.
6. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
7. 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 swab is not adequate or is below the detectable level of the test.
8. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result.
9. 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.
10. 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.
11. Positive results may be due to present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
12. 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.

2. PERFORMANCE CHARACTERISTICS

2.1. Sensitivity, Specificity and Accuracy

The COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) 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 (Nasopharyngeal Swab). Specimens were considered positive if PCR indicated a positive result.

Method		RT-PCR		Total Results
Sienna™ COVID-19 Antigen Rapid Test Cassette	Results	Positive	Negative	
	Positive	30	3	33
	Negative	2	360	362
	Total Results	32	363	395

Relative Sensitivity:	93.8% (95% CI: 79.2% – 99.2%)
Relative Specificity:	99.2% (95% CI: 97.6% – 99.8%)
Relative Accuracy:	98.7% (95% CI: 97.1% – 99.6%)

2.2. Limit of Detection

The LOD for the Sienna™ COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) was established using limiting dilutions of a viral sample inactivated. The Estimated LOD is 4.0×10^3 $TCID_{50}$/mL.

SARS-CoV-2 tested ($TCID_{50}$/mL)	**Test Result**
3.17×10^4TCID 50/mL	3/3 Positive
1.58×10^4TCID 50/mL	3/3 Positive
1.06×10^4TCID 50/mL	3/3 Positive
3.96×10^3 TCID 50/mL	3/3 Positive
1.58×10^3TCID 50/mL	3/3 Negative

2.3. Cross Reactivity

The following potentially cross-reactive substances were added to SARS-CoV-2 negative and spiked positive specimens. The organisms or viruses do not cross-react.

Potential Cross-Reactant	Concentration	Results	
		Negative Specimen	Spiked with Positive Specimen
Adenovirus (e.g. C1 Ad. 71)-Type 7A	1.41×10^5 U/ml	Negative	Positive
Enterovirus (e.g. EV68)	5.01×10^5 $TCID_{50}$/ml	Negative	Positive
Human Metapneumovirus (hMPV)	3.80×10^6 $TCID_{50}$/ml	Negative	Positive
Influenza A H1N1 (New Cal/20/99)	1.15×10^7 U/ml	Negative	Positive
Influenza B (Florida/02/06)	1.41×10^5 U/ml	Negative	Positive
Parainfluenza virus 1	9.12×10^8 $TCID_{50}$/ml	Negative	Positive
Parainfluenza virus 2	1.15×10^7 U/ml	Negative	Positive
Parainfluenza virus 3	6.61×10^6 U/ml	Negative	Positive
Parainfluenza virus 4	2.82×10^7 U/ml	Negative	Positive
Respiratory syncytial virus-Type A	3.80×10^6 U/ml	Negative	Positive
Rhinovirus (Type 1A)	3.55×10^5 U/ml	Negative	Positive
Bordetella pertussis	1.13×10^{10} CFU/ml	Negative	Positive
Candida albicans	6.27×10^8 CFU/ml	Negative	Positive
Haemophilus influenzae	5.43×10^8 CFU/ml	Negative	Positive
Legionella pneumophila	1.88×10^{10} CFU/ml	Negative	Positive
Mycobacterium tuberculosis	6.86×10^7 CFU/ml	Negative	Positive
Mycoplasma pneumoniae	3.16×10^8 CCU/ml	Negative	Positive
Pneumocystis jirovecii (PJP)-S. cerevisiae Recombinant	3.45×10^8 CFU/ml	Negative	Positive
Pseudomonas aeruginosa	8.44×10^9 CFU/ml	Negative	Positive
Staphylococcus epidermis	1.21×10^{10} CFU/ml	Negative	Positive
Streptococcus pneumoniae	2.26×10^9 CFU/ml	Negative	Positive
Streptococcus pyogenes	1.64×10^9 CFU/ml	Negative	Positive
Streptococcus salivarius	8.17×10^8 CFU/ml	Negative	Positive
Human coronavirus 229E	4.17×10^5 $TCID_{50}$/ml	Negative	Positive
Human coronavirus OC43	1.05×10^6 $TCID_{50}$/ml	Negative	Positive
Human coronavirus NL63	1.70×10^5 $TCID_{50}$/ml	Negative	Positive
MERS-coronavirus	3.16×10^6 $TCID_{50}$/ml	Negative	Positive
Influenza A Virus H3N2	1.6×10^5CEID/ml	Negative	Positive

3. EXPLANATION OF THE SYMBOLS USED

IVD	For in vitro diagnostic use
REF	Catalogue number
LOT	Batch code
	Manufacturer
	Date of manufacture
	Use by
	Do not use if package is damaged
	Consult instruction for use
	Temperature limit at 2°C – 30°C.
	Contents sufficient for n tests
	Do not re-use
	Caution
	Keep dry
	Protect from direct sunlight
CE	CE Mark

4. REFERENCES

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5. DATE OF ISSUE

Sienna™ COVID-19 Antigen Rapid Test Cassette insert.

Version 2, September 29th, 2020

6. GENERAL INFORMATION

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