COVID-19 EUA Rapid Antigen Test

Sienna COVID-19 Antigen Rapid Test Cassette

Sienna COVID-19 Rapid Antigen Test

Product Details

Sienna COVID-19 Rapid Antigen Test Specifications	
EUA Number:	EUA210062
Result Time:	10 minutes
Authorized Use:	For professional in vitro diagnostic use only
LOD:	1.25X 10^3 $TCID_{50}$/ml
Individual Buffer Vials:	Helping multiple operators at same time
Specimens Obtained Through:	Direct nasopharyngeal swab
Each Kit Includes:	• 1 instructions for use • 25 individually pouched test cassettes • 25 buffer tubes • 25 sterile swabs
Positive Predictive Value:	100% with CT Value - 21-33
Negative Predictive Value:	98.9% with CT Value - 21-33
Manufacturer:	Salofa Oy
Manufacturing Country:	Finland
FDA EUA Letter:	Link
Instructions for Use:	Link

Sienna COVID-19 Rapid Antigen Test

Product Photos

Applications

Quickly screen people for COVID-19 at CLIA-certified labs, places of work, universities and schools, airports and train stations, stadiums, hotels, cruise ships and tours.

As a reminder: these tests are for professional in vitro diagnostic use only.

Health Systems

Schools & Universities

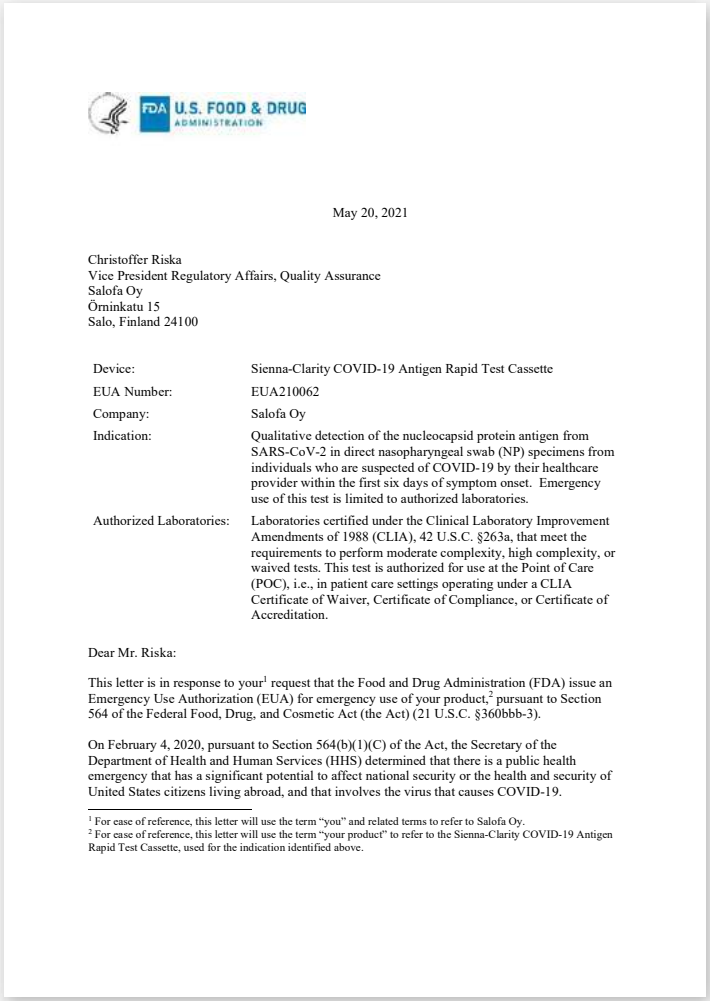
Cruises & Tours

Workplace & Buildings

Stadiums & Festivals

Bus, Train and Plane terminals

FDA Emergency Use Auhorization (EUA) Letter



U.S. FOOD & DRUG ADMINISTRATION

May 20, 2021

Christoffer Riska
Vice President Regulatory Affairs, Quality Assurance
Salofa Oy
Örninkatu 15
Salo, Finland 24100

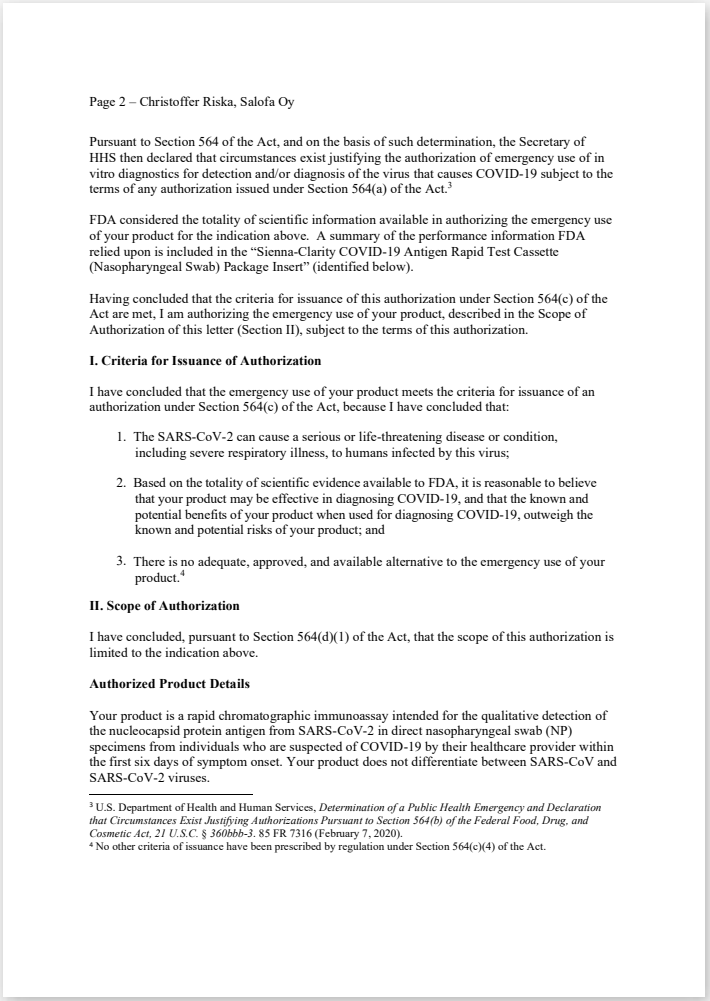
Device:	Sienna-Clarity COVID-19 Antigen Rapid Test Cassette
EUA Number:	EUA210062
Company:	Salofa Oy
Indication:	Qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in direct nasopharyngeal swab (NP) specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first six days of symptom onset. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate complexity, high complexity, or waived tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Dear Mr. Riska:

This letter is in response to your[1] request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,[2] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19.

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Salofa Oy.
[2] For ease of reference, this letter will use the term "your product" to refer to the Sienna-Clarity COVID-19 Antigen Rapid Test Cassette, used for the indication identified above.



Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.[3]

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is included in the "Sienna-Clarity COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) Package Insert" (identified below).

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product.[4]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

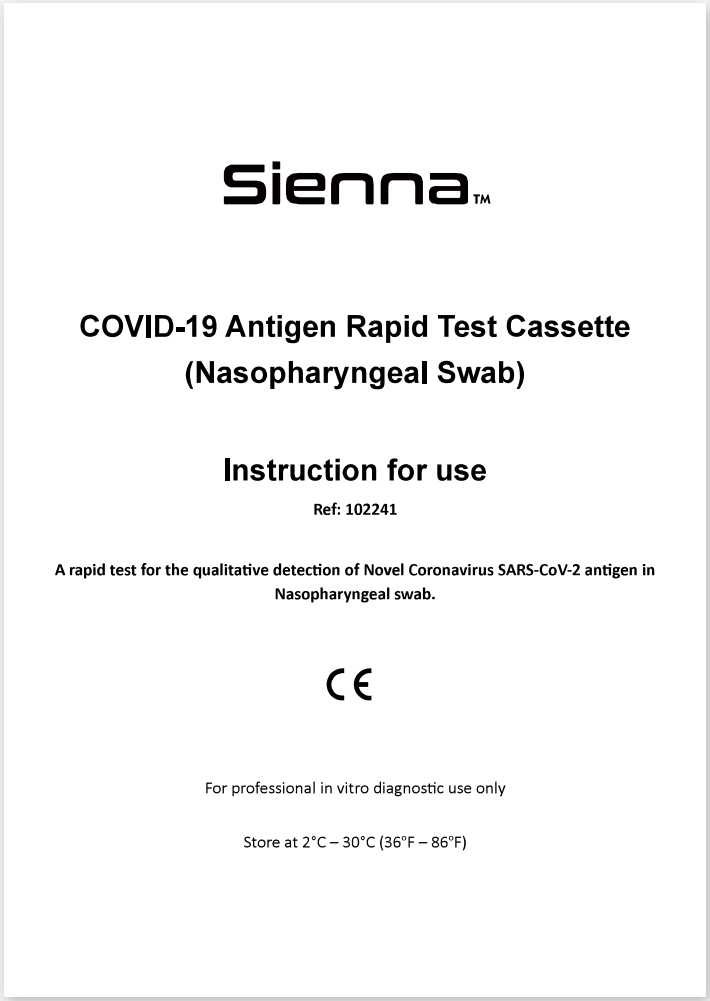
Authorized Product Details

Your product is a rapid chromatographic immunoassay intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in direct nasopharyngeal swab (NP) specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first six days of symptom onset. Your product does not differentiate between SARS-CoV and SARS-CoV-2 viruses.

[3] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. 85 FR 7316 (February 7, 2020).
[4] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

FDA EUA Letter

Instructions for Use



Sienna™

COVID-19 Antigen Rapid Test Cassette
(Nasopharyngeal Swab)

Instruction for use

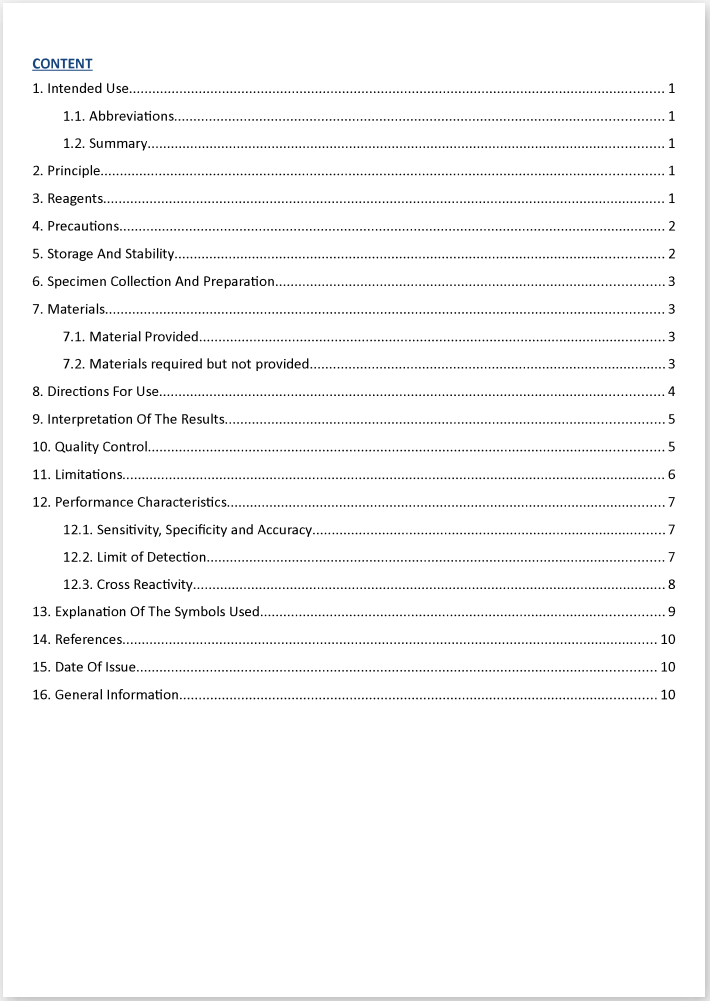
Ref: 102241

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

Instructions for Use

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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.

Instructions for Use

Instructions for Use

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

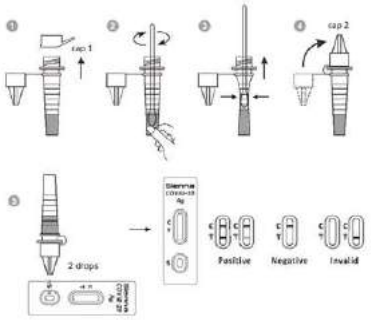
Timer

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.



Instructions for Use

Instructions for Use

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 coronavirus strains.
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.

Instructions for Use

12. PERFORMANCE CHARACTERISTICS

12.1. 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%)

12.2. 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^{4}TCID 50/mL	3/3 Positive
1.58×10^{4}TCID 50/mL	3/3 Positive
1.06×10^{4}TCID 50/mL	3/3 Positive
3.96×10^{3} TCID 50/mL	3/3 Positive
1.58×10^{3}TCID 50/mL	3/3 Negative

12.3. 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^{5} $TCID_{50}$/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^{8} 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^{5}CEID/ml	Negative	Positive

Instructions for Use

13. 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

14. REFERENCES

[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.

[4] WHO. Coronavirus disease 2019 (COVID-19) Situation Reports. Available from: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports

[5] Liu L, Liu W et al. A preliminary study on serological assay for severe acute 2 respiratory syndrome coronavirus 2 (SARS-CoV-2) in 238 3 admitted hospital patients. Available from: https://www.medrxiv.org/content/10.1101/2020.03.06.20031856v1.full.pdf

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[7] Juan juan Zhao et.al, Antibody responses to SARS-CoV-2 in patients of novel coronavirus disease 2019, Clinical Infectious Diseases, ciaa344,http://doi.org/10.1093/cid/ciaa344.

[8] Structure, function and antigenicity of the SARS-CoV-2 spike glycoprotein. Journal pre-proof DOI:10.1016/j.cell. 2020.02.058.

[9] US Food and Drug Administration (FDA). Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency. Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff. Issued March 16, 2020. Docket Number FDA-2020-D-0987.

15. DATE OF ISSUE

Sienna™ COVID-19 Antigen Rapid Test Cassette insert.

Version 2, September 29th, 2020

16. GENERAL INFORMATION

Manufacturer:

Salofa Oy
Örninkatu 15, 24100 Salo, Finland
email: info@salofa.com
web: www.salofa.com

Contact Us

Sienna COVID-19 Antigen Rapid Test Cassette

Place Order

Request Samples