Innovative Diagnostic Solutions for Today's Healthcare

Sienna COVID-19 Antigen Rapid Test Kit

Results in 10 minutes using a Nasopharyngeal swab

Test Details

The Sienna 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 for professional in-vitro diagnostic use only.

Accurate Results

- Sensitivity: 95.0%
- Specificity: 99.2%
- Accuracy: 98.8%

Unmatched Convenience

- Visual Results: Easy to interpret.
- Fast Results: 10-minute test time.
- Individual Buffer Vials and Sterile Swabs:
  Helps in testing multiple individuals simultaneously.

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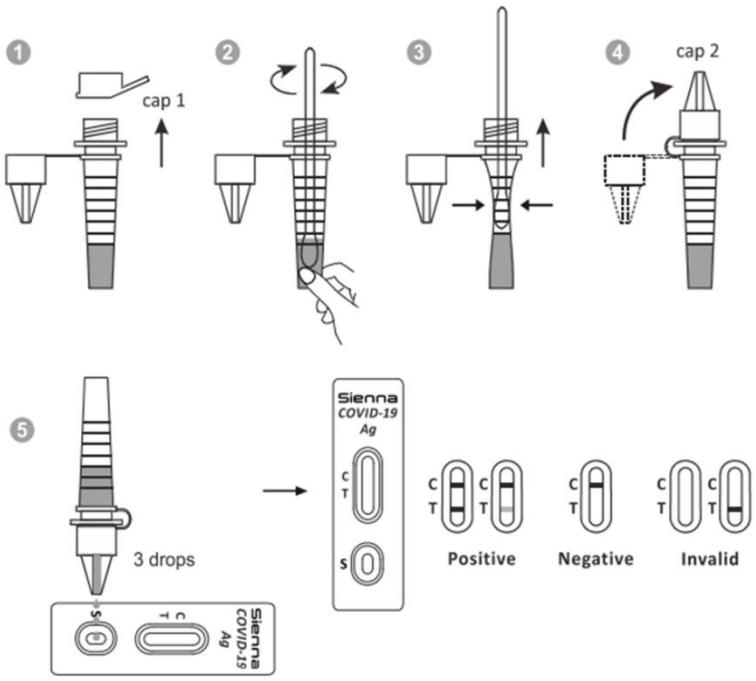
Sienna COVID-19 Antigen Rapid Test Kit

During the testing process, the extracted specimen reacts with the antibody of the SARS-CoV-2 nucleocapsid protein that are coated onto particles. The mixture migrates into the membrane to react with the antibody for the SARS-CoV-2 nucleocapsid protein on the membrane and will generate one colored line in the test regions. The presence of this colored line in the test regions indicates a positive result. A colored line will always appear in the control region to serve as a procedural control if the test has been performed correctly.

Test Procedure



Kit Contains:

- (1) IFU
- (25) Individually pouched Cassettes
- (1) Workstation
- (25) Buffer Tubes
- (25) Sterile Swabs

Order and Shipping Information

Cat. No.	Product:	QTY	Registration Status
102242	Sienna COVID-19 Antigen Rapid Test Contents: (1) IFU (25) Individually pouched Cassettes (1) Workstation (25) Buffer Tubes (25) Sterile Swabs	25 Tests	CE EUA Authorized May 2021

Item	Quantity	Length		Width		Height		Box Weight	
Box	25 Tests	5	in	9.35	in	2.66	in	0.57	lbs
		12.25	cm	23.75	cm	6.75	cm	0.26	kg
Carton	49 Boxes (1,225 test)	24	in	16	in	20	in	46	lbs
		60	cm	40	cm	50	cm	20.8	kg
Pallet Option 1	8 Cartons 9,800	48	in	42	in	72	in	370	lbs
		120	cm	105	cm	180	cm	170	kg
NOTE: Total weight of Product Approx. (200kg) AND Pallet + other packaging (25kg) together = 200 kg Air Passenger Plane Cargo Only.									
Pallet Option 2	12 Cartons 14,700	48	in	42	in	72	in	550	lbs
		120	cm	105	cm	180	cm	250	kg
NOTE: Total weight of Product (265kg) AND Pallet (11kg) together = 265 kg Air Freight Cargo Only									
Pallet Option 3	16 Cartons 19,600	48	in	42	in	72	in	575	lbs
		120	cm	105	cm	180	cm	260	kg
NOTE: Total weight of Product Approx. (260kg) AND Pallet + other packaging (25kg) together = 300 kg Air Cargo Freight Only Short Height.									

SALOFA OY
Örninkatu 15, 24100 Salo, Finland
www.salofa.com

Establishment Registration & Device Listing

New Search | Back To Search Results

Establishment:
SALOFA OY
Orninkatu 15
Salo Pirkanmaa, FI 24100
Registration Number: 3016820006
FEI Number*: 3016820006
Status: Active
Date Of Registration Status: 2021

Owner/Operator:
Salofa Oy
Orninkatu 15
Salo, Pirkanmaa FI 24100
Owner/Operator Number: 10071162

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* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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.

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[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.

The SARS-CoV-2 nucleocapsid protein antigen is generally detectable in NP swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses.

Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

Testing of NP swab specimens using your product, as outlined in the "Sienna-Clarity COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) Package Insert" is limited to laboratories certified under CLIA 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.

To use your product, the direct NP swab specimen is first placed into the extraction buffer for 1 minute to elute the specimen from the swab before removing the swab and capping the tube. The extracted solution is then applied to the test cassette where it is first exposed to particles coated with antibody to nucleocapsid protein of SARS-CoV-2 before the mixture migraties on the membrane towards the test line, functionalized with antibody to nucleocapsid protein of SARS-CoV-2, and the control line. If SARS-CoV-2 nucleocapsid antigen is present in a patient sample, a colored line will appear in the test line region. A colored line at the control region should always appear if the assay is performed correctly.

The Sienna-Clarity COVID-19 Antigen Rapid Test Cassette includes the following materials or other authorized materials: Test cassettes, Extraction Tubes, Sterile Nasopharyngeal swabs, Workstation, Positive Control Swab, and Negative Control Swab.

Your product requires various types of quality control, including the procedural internal control that is built in the 'control line (c)' of the test device and the external positive and negative controls, or other authorized control materials (as may be requested under Condition N. below), that are processed in the same way as the patient samples. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the Package Insert:

- Positive Control Swab - 100 pg/ml recombinant SARS-CoV-2 nucleocapsid protein in extraction buffer
- Negative Control Swab - 0.5% BSA-PBS solution

Your product also requires the use of additional authorized materials and authorized ancillary reagents that are not included with your product and are described in the Package Insert.

The labeling entitled "Sienna-Clarity COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) Package Insert", "Quick User Guide (Sienna-Clarity COVID-19 Antigen Rapid Test Cassette" (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas), and the following fact sheets pertaining to the emergency use, is required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as "authorized labeling":

- Fact Sheet for Healthcare Providers: Salofa Oy - Sienna-Clarity COVID-19 Antigen Rapid Test Cassette
- Fact Sheet for Patients: Salofa Oy - Sienna-Clarity COVID-19 Antigen Rapid Test Cassette

The above described product, when accompanied by the authorized labeling provided as set forth in the Conditions of Authorization (Section IV), is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing COVID-19, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, your product is authorized for the indication above.

III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture,

packaging, labeling, storage, and distribution of your product, but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

Salofa Oy (You) and Authorized Distributor(s)[5]

A. Your product must comply with the following labeling requirements under FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 CFR 809.10(b)(5), (7), and (8)); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

B. You and authorized distributor(s) must make your product available with the authorized labeling to authorized laboratories.

C. You and authorized distributor(s) must make available on your website(s) the authorized labeling.

D. You and authorized distributor(s) will include a physical copy of the "Sienna-Clarity COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) Package Insert" and the "Quick User Guide (Sienna-Clarity COVID-19 Antigen Rapid Test Cassette" with each shipped kit of your product to authorized laboratories.

E. You and authorized distributor(s) must inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and authorized labeling.

F. Through a process of inventory control, you and authorized distributor(s) must maintain records of the authorized laboratories to which they distribute your product and number distributed.

G. You and authorized distributor(s) must collect information on the performance of your product. You will report to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)-Office of In Vitro Diagnostics and Radiological Health (OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) any suspected occurrence of false positive or false negative

[5] "Authorized Distributor(s)" are identified by you, Salofa Oy, in your EUA submission as an entity allowed to distribute your product.

results and significant deviations from the established performance characteristics of the product of which you become aware.

H. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

Salofa Oy (You)

I. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

J. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent revisions that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).

K. You must comply with the following requirements pursuant to FDA regulations: 21 CFR 820 Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

L. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the tests released for distribution have the clinical and analytical performance claimed in the authorized labeling.

M. If requested by FDA, you must submit lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide it within 48 hours of the request.

N. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling, and shall not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to DMD/OHT7-OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

O. You must evaluate the analytical limit of detection and assess traceability[6] of your product with any FDA-recommended reference material(s). After submission to and review and concurrence with the data by FDA, you must update labeling to reflect the additional testing. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

[6] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

P. You must have a process in place to track adverse events, including any occurrence of false results and report to FDA pursuant to 21 CFR Part 803.

Authorized Laboratories

Q. Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating this labeling may be used, which may include mass media.

R. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including authorized instruments, authorized clinical specimen types, authorized control materials, authorized ancillary reagents and authorized materials required to use your product are not permitted.

S. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.

T. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

U. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov), and you (info@salofa.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.

V. All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

Salofa Oy (You), Authorized Distributor(s) and Authorized Laboratories

W. You, authorized distributor(s), and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

Conditions Related to Printed Materials, Advertising and Promotion

X. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act and FDA implementing regulations.

Y. No descriptive printed matter, advertising, or promotional materials relating to the use of your product may represent or suggest that this test is safe or effective for the

detection of SARS-CoV-2.

Z. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories;
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and,
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

Denise M. Hinton -S

Digitally signed by Denise M. Hinton -S
Date: 2021.05.20 13:21:30 -04'00'

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure