Sienna™

COVID-19 Antigen Rapid Test Cassette REF 102242

Quick User Guide

For Use Under the Emergency Use Authorization Only (EUA).
For professional in-vitro diagnostic use only.
For prescription use only

A rapid test for the qualitative detection of novel coronavirus SARS-CoV-2 antigen in nasopharyngeal swab.
Please refer to the package insert for detailed assay instructions, cautions, limitations and warnings.

INTENDED USE

The Sienna™ COVID-19 Antigen Rapid Test Cassette 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.

Testing is limited to 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.

The Sienna™ COVID-19 Antigen Rapid Test Cassette does not differentiate between SARS-CoV and SARS-CoV-2 viruses.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in nasopharyngeal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient 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. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

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.

The Sienna™ COVID-19 Antigen Rapid Test Cassette is intended for use by trained clinical laboratory personnel and individuals trained in point of care. The Sienna™ COVID-19 Antigen Rapid Test Cassette is only for use under the Food and Drug Administration's Emergency Use Authorization.

BEFORE YOU BEGIN

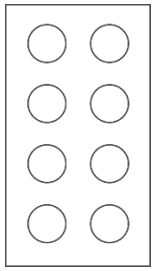
1. If the test kit has been stored in the refrigerator, allow all kit component(s) to equilibrate to room temperature before use.
2. Read through the entire User Quick Reference Guide before beginning a test. Refer to the Instruction for Use for more information.

Manufactured by: Salofa Oy Örninkatu 15, 24100 Salo, Finland, www.salofa.com, info@salofa.com
US Technical Support: 1-877-453-0537, technical@seroclinix.com

Materials required for testing

Extraction buffer tube

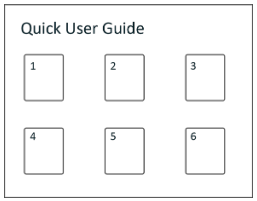
Sterile swab



Workstation

Test cassette

Instruction for use



Quick User Guide

Timer

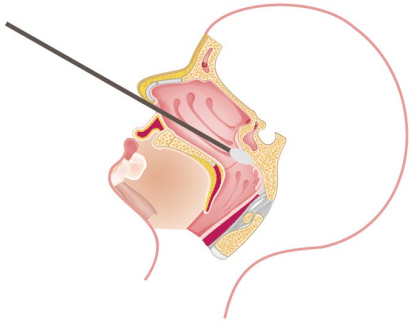
Gloves

SPECIMEN COLLECTION

Notes:

- **Collect the specimen immediately after opening the swab packaging.**
- **Do not touch the head of the swab.**
- **Process the test specimen immediately after collection.**

1. Tilt patient's head back 70 degrees.
2. Gently and slowly insert the swab with a flexible shaft (wire or plastic) 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.
3. Gently rub and roll the swab.
4. Leave swab in place for several seconds to absorb secretions.
5. 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 minitip is saturated with fluid from the first collection.
6. 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.
7. Place swab, tip first, into a dry tube or directly into the extraction buffer tube.



For more info, please visit: https://www.cdc.gov/coronavirus/2019-ncov/downloads/lab/NP_Specimen_Collection_Infographic_FINAL_508.pdf

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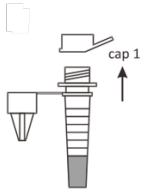
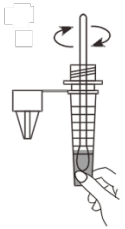
TEST PROCEDURE

Notes:

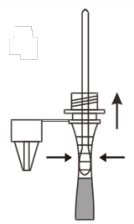
- **Allow test cassette, specimen, and extraction buffer to reach room temperature prior to testing.**
- **Remove the test cassette from the sealed pouch and use it within 1 hour. Best results will be obtained if the test is performed immediately after opening the pouch.**



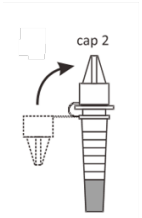
1. Place the extraction buffer in the workstation. Open cap 1 by pulling cap 1 upwards.



2. Place the swab head in the extraction buffer. Rotate the swab for approx. 10 seconds while pressing the head against the inside of the tube. Leave the swab in the extraction buffer for 1 minute.

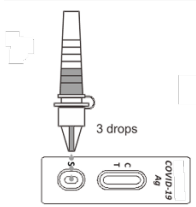


3. Remove the swab from the tube while squeezing the swab against the inside of the tube to expel as much liquid as possible from the swab. Discard the swab



4. Tighten cap 2 by pushing firmly onto the vial.

5. Remove the test cassette from the sealed pouch and place it on a level surface.



6. Invert the extraction tube. Holding the extraction tube vertically above the sample well (S), add three (3) drops of solution into the sample well.
Immediately after adding the solution to the sample well, set the timer for 10 minutes and start the timer.

RESULT INTERPRETATION

Read result at 10 minutes. Do NOT interpret the result after 20 minutes.*

Negative

One colored line appears in the control line region (C). No line appears in the test line region (T).

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).

Invalid

No line appears in the control line region (C) and the test line region (T).

OR

One colored line in the test line region (T) and o line in the control line region (C)

*Note: A negative result is presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed.

*Note: Erroneous results can occur if the test results are read before or after 10-20 minutes.

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STORAGE AND STABILITY

The test kit should be stored 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.

EXTERNAL QUALITY CONTROL

Positive and Negative Control standards are supplied with this kit; it is recommended that positive and negative controls be tested as a good laboratory practice with every new lot, shipment, or a new operator.

To perform a control test, remove the control swabs from the packaging and follow the instructions under "TEST PROCEDURE" and interpret the result as per "INTERPRETATION OF RESULTS". If the correct control results are not obtained, do not perform patient testing or report patient results. Contact us at 1-877-485-7877/ email info@salofa.com

ASSISTANCE

For any enquiries regarding the Sienna™ COVID-19 Antigen Rapid Test Cassette, please contact us at:

Email: info@salofa.com

OR

Email: technical@seroclinix.com/ 1 -877-453-0537 (US)

In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests. This product 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.

This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and in the USA, 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 the virus that causes COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless declaration is terminated or the authorization is revoked sooner.