

**Sienna-Clarity COVID-19 Antigen Rapid Test Cassette
(Nasopharyngeal Swab)**

Package Insert

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

For prescription use only

For in vitro diagnostic use

For use under the Emergency Use Authorization (EUA) only

INTENDED USE

The Sienna-Clarity 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 6 days of symptom onset when tested at least twice over three days with at least 48 hours between tests.

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-Clarity 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, which 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 definitive cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

All negative results are 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 measures, such as isolating from others and wearing masks. Negative results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

The Sienna-Clarity COVID-19 Antigen Rapid Test Cassette is intended for use by healthcare professionals or operators who are proficient in performing tests in point of care settings. The Sienna-Clarity COVID-19 Antigen Rapid Test Cassette is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

SUMMARY

SARS-CoV-2: novel coronavirus

COVID-19: novel coronavirus pneumonia

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 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 can be used as a supplementary test for nucleic acid testing.

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.

REAGENTS

The test cassette contains antibodies against SARS-CoV-2 Nucleocapsid protein coated on the membrane.

WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION

1. Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
2. In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. 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.
3. **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
4. Laboratories within the United States and its territories are required to report all results to the appropriate public health laboratories.
5. Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
6. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
7. Do not store this kit in frozen condition
8. Do not use if any of the test kit contents or packaging is damaged.
9. Test components are single-use. Do not re-use.
10. Do not use kit past its expiration date.
11. Do not touch the swab tip.
12. Do not eat, drink or smoke in the area where the specimens or kits are handled.
13. Allow the test cassette, specimen, supporting buffer to equilibrate to room temperature 15°C – 30°C (59°F – 86°F) prior to testing.
14. Once opened, the test card should be used within 60 minutes.
15. Do not read test results before 10 minutes or after 20 minutes. Results read before 10 minutes or after 20 minutes may lead to a false positive, false negative, or invalid result.
16. The used tests, specimens and potentially contaminated material should be discarded according to the local regulations.

17. Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your skin, eyes, nose, or mouth. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your skin, eyes, nose, or mouth, flush with large amounts of water.

18. **If irritation persists, seek medical advice: <https://www.poisonhelp.org> or 1-800-222-1222.**

| Chemical Name | GHS Code for each Ingredient | Concentrations |
|---------------|---|----------------|
| Tris | H315 - Causes skin irritation H319 - Causes serious eye irritation H335 - May cause respiratory irritation | 0.3% |
| Proclin™ 300 | H332 Harmful if inhaled. H302 Harmful if swallowed H314 Causes severe skin burns and eye damage H317 May cause an allergic skin reaction | 0.03% |

For more information on EUAs please visit:

<https://www.fda.gov/emergencypreparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergencyuse-authorization>

For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

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.

MATERIALS

Materials provided

25 Test cassettes 25 Extraction Tubes (NaCl + Casein Sodium + Tris + Proclin 300)
25 Sterile Nasopharyngeal swabs 1 Package Insert 1 Quick User Guide 1 Workstation
1 Positive Control Swab 1 Negative Control Swab

MATERIALS REQUIRED BUT NOT PROVIDED

Timer Gloves

Additional control swabs (1 positive + 1 negative control swab) can be purchased separately.

Clarity Catalog Number: CLA-COV19AG-CTLP/ CLA-COV19AG-CTLN

Sienna Catalog Number: 10224PS/10224NS

SPECIMEN TRANSPORT AND STABILITY

For the best results, specimen should be tested immediately after collection. If collected specimen cannot be tested immediately, the swabs can be stored in a dry tube at room temperature for no longer than 1 hour and at 2-8°C for no longer than 24 hours.

Test should be performed immediately after adding the swab into the extraction tube.

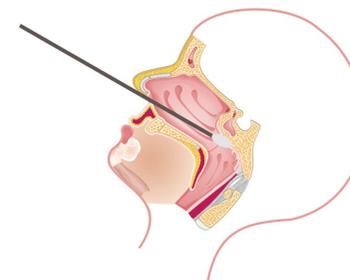
SPECIMEN COLLECTION

The COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) can be performed using nasopharyngeal swab specimens. The quality of specimens obtained is of extreme importance. Detection of COVID-19 Antigen requires a vigorous and thorough collection technique that provides COVID-19 Antigen rather than just body fluids.

To collect Nasopharyngeal swab Specimen:

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.



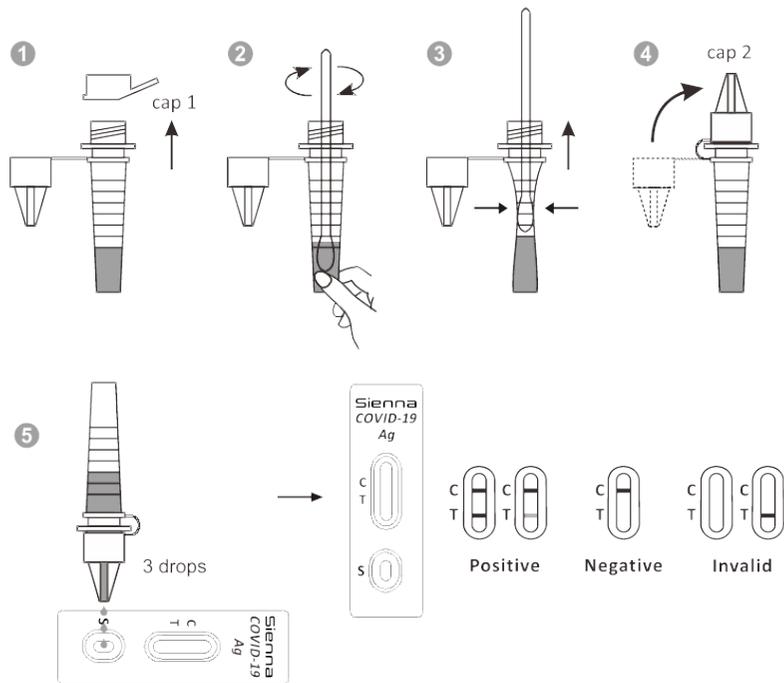
For more information, visit:

https://www.cdc.gov/coronavirus/2019-ncov/downloads/lab/NP_Specimen_Collection_Infographic_FINAL_508.pdf

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.
 7. Immediately after adding the solution to the sample well, set the timer for 10 minutes and start the timer.



TEST INTERPRETATION

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results for COVID-19.

| Status on First Day of Testing | First Result Day 1 | Second Result Day 3 | Interpretation |
|--------------------------------|--------------------|---------------------|-----------------------|
| With Symptoms | Positive | N/A | Positive for COVID-19 |
| | Negative | Positive | Positive for COVID-19 |
| | Negative | Negative | Negative for COVID-19 |

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

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

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.

COVID-19 NEGATIVE (-)

If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.

To increase the chance that the negative result for COVID-19 is accurate, you should:

- **Test again in 48 hours if the individual has symptoms on the first day of testing.**

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. 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.



COVID-19 POSITIVE (+):

If the Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible reddish-purple test (T) line with the control line (C) should be read as positive.

Repeat testing does not need to be performed if patients have a positive result at any time.

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care



physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

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. Individuals who test positive with the Sienna-Clarity COVID-19 Antigen Rapid Test Cassette should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

INVALID:

If the control (C) line is not visible, the test is invalid. Re-test with a new swab and new test device.



Invalid

QUALITY CONTROL

An internal procedural control is included in the test. A line appearing in the control line region (C) is an internal valid procedural control, and it confirms adequate membrane wicking. 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 “DIRECTION FOR USE” and interpret the result as per “TEST INTERPRETATION”. If the correct control results are not obtained, do not perform patient testing or report patient results. Contact the US Technical Support at 1-877-485-7877/covid19techsupport@claritydiagnostics.com

LIMITATIONS

1. The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between November 2020 and December 2020. The clinical performance has not been established for all circulating variants but is anticipated to be

reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

2. There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
3. All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary.
4. If the patient continues to have symptoms of COVID-19, and both the patient’s first and second tests are negative, the patient may not have COVID-19, however additional follow-up may be needed.
5. If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and the individual likely has COVID-19.
6. This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
7. Incorrect test results may occur if a specimen is incorrectly collected or handled.
8. This test detects both viable (live) and nonviable SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample.
9. This device is for professional in vitro diagnostic use only.
10. This device is only used for testing direct human nasopharyngeal swab specimens. Viral transport media (VTM) should not be used with this test.
11. Avoid using samples with visible blood on the swab.
12. Not for use in at-home testing settings.
13. Neither the quantitative value nor the rate of increase in SARS-CoV-2 virus concentration can be determined by this qualitative test.
14. 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.
15. The COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) will indicate the presence of SARS-CoV-2 in the specimen from both viable and non-viable SARS-CoV-2 coronavirus strains.

16. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
17. Positive test results do not rule out bacterial infection or co-infection with other viruses.
18. Negative test results do not rule out bacterial infection or co-infection with other viruses.
19. Positive results may be due to present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1 and SARS-CoV.

CONDITIONS OF AUTHORIZATION FOR THE LABORATORY

The Sienna-Clarity COVID-19 Antigen Rapid Test Cassette Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website:

<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>. However, to assist clinical laboratories using the Sienna-Clarity COVID-19 Antigen Rapid Test Cassette (“your product” in the conditions below), the relevant Conditions of Authorization are listed below:

- A. Authorized laboratories* using your product must include, with test result reports, all Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- B. Authorized laboratories using your product must use your product as outlined in the “authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
- C. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating tests.
- D. 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.
- E. 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 Salofa Oy (via email: 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.
- F. 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 labeling.

G. Salofa Oy and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by the FDA. Such records will be made available to the FDA for inspection upon request.

*The letter of authorization refers to, “Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high, moderate or waived complexity tests. This test is authorized for use at the Point of Care (POC) i.e. in patient care settings operating under CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation” as “authorized laboratories.”

PERFORMANCE CHARACTERISTICS

Limit of Detection - LOD

The LOD for the Sienna-Clarity COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab) was established using serial dilutions of an inactivated viral sample (ZeptoMetrix, 0810587CFHI) in natural nasal clinical matrix. Contrived nasal swab samples were prepared by absorbing 50 microliters of each virus dilution onto the swab. The contrived swab samples were tested according to the test procedure. The LOD was determined as the lowest virus concentration that was detected $\geq 95\%$ of the time (i.e., concentration at which at least 19 out of 20 replicates tested positive). The determined LOD is 1.25×10^3 TCID₅₀/mL, which is equivalent to 62.5 TCID₅₀/swab.

NIH/RADx Variant Testing

The performance of this device in the detection of the Omicron variant of SARS-CoV-2 was evaluated in a dilution series of clinical specimens which were positive for the Omicron variant. This testing was conducted by the National Institutes of Health (NIH) as a component of the Rapid Acceleration of Diagnostics (RADx®) initiative. The clinical specimens used to prepare this dilution series were not identical to the previous specimen pools prepared and tested by RADx to assess performance with the omicron variant. Results from this dilution series cannot be compared to other specimen pools and do not indicate that a test will have different clinical performance compared to other EUA authorized tests. Compared to an EUA authorized RT-PCR method, this device detected 100% of live virus Omicron samples at a Ct-value of 25.4 (n=5). Omicron dilutions at lower viral concentrations (Ct-values greater than 26.7) were not detected by the device in this study.

| Sample | AVG N2-Ct n=9 | STDEV n=9 | Replicates | | | | | % Positive |
|--------------------|------------------|--------------|------------|-----|-----|-----|-----|------------|
| | | | 1 | 2 | 3 | 4 | 5 | |
| BQ 1.1 Dilution 1 | 18.0 | 0.27 | Pos | Pos | Pos | Pos | Pos | 100 |
| BQ 1.1 Dilution 2 | 19.4 | 0.10 | Pos | Pos | Pos | Pos | Pos | 100 |
| BQ 1.1 Dilution 3 | 20.0 | 0.22 | Pos | Pos | Pos | Pos | Pos | 100 |
| BQ 1.1 Dilution 4 | 21.5 | 0.05 | Pos | Pos | Pos | Pos | Pos | 100 |
| BQ 1.1 Dilution 5 | 23.0 | 0.14 | Pos | Pos | Pos | Pos | Pos | 100 |
| BQ 1.1 Dilution 6 | 24.4 | 0.20 | Pos | Pos | Pos | Pos | Pos | 100 |
| BQ 1.1 Dilution 7 | 25.4 | 0.06 | Pos | Pos | Pos | Pos | Pos | 100 |
| BQ 1.1 Dilution 8 | 26.7 | 0.15 | Neg | Neg | Neg | Neg | Neg | 0 |
| BQ 1.1 Dilution 9 | 27.7 | 0.09 | Neg | Neg | Neg | Neg | Neg | 0 |
| BQ 1.1 Dilution 10 | 28.7 | 0.16 | Neg | Neg | Neg | Neg | Neg | 0 |
| BQ 1.1 Dilution 11 | 29.8 | 0.02 | Neg | Neg | Neg | Neg | Neg | 0 |
| BQ 1.1 Dilution 12 | 30.6 | 0.76 | Neg | Neg | Neg | Neg | Neg | 0 |
| Negative Control | 0.0 | - | Neg | Neg | Neg | Neg | Neg | 0 |
| Negative Control | 0.0 | - | Neg | Neg | Neg | Neg | Neg | 0 |
| Negative Control | 0.0 | - | Neg | Neg | Neg | Neg | Neg | 0 |

Clinical Performance: Prospective Serial Testing Study at National Institutes of Health:

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS- CoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 - 48 hours apart.

Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RT- PCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Pre-symptomatic subjects were included in the positive percent agreement (PPA) of asymptomatic individuals, if they were asymptomatic on the first day of antigen testing, regardless of whether they developed symptoms at any time after the first day of testing.

Performance of the antigen test with serial testing in individuals is described in Table 2.

Table 2: Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.

| Days After First PCR Positive Test Result | Symptomatic on First Day of Testing | | |
|---|--|---------------|---------------|
| | Ag Positive/ PCR Positive (Antigen Test Performance % PPA) | | |
| | 1 Test | 2 Tests | 3 Tests |
| 0 | 34/57 (59.6%) | 47/51 (92.2%) | 44/47 (93.6%) |
| 2 | 58/62 (93.5%) | 59/60 (98.3%) | 43/43 (100%) |
| 4 | 55/58 (94.8%) | 53/54 (98.1%) | 39/40 (97.5%) |
| 6 | 27/34 (79.4%) | 26/33 (78.8%) | 22/27 (81.5%) |
| 8 | 12/17 (70.6%) | 12/17 (70.6%) | 7/11 (63.6%) |
| 10 | 4/9 (44.4%) | 3/7 (42.9%) | |

1 Test = one (1) test performed on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.

2 Tests = two (2) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.

3 Tests = three (3) tests performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test

Clinical Evidence

To evaluate the performance of the Sienna-Clarity COVID-19 Antigen Rapid Test Cassette at a POC setting, a prospective, non-interventional study was performed with 133 nasopharyngeal swab samples. The samples were sequentially collected from 133 symptomatic patients who presented symptoms of COVID-19 infection within 7 days of symptom onset, at one POC site in the United States, from November to December, 2020. All tests were performed by 5 non-laboratory healthcare providers (2 medical assistants, 1 registered nurse, 1 radiography

technician, and 1 clinical trial coordinator) who were only provided with a Quick Reference Guide and the Instruction for Use on how to use the test and interpret the results. Two (2) nasopharyngeal swabs specimens (one for RT-PCR confirmation, and the another for antigen rapid test) were then collected randomly from each nostril. An US FDA EUA authorized RT-PCR was 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.

| | |
|-----------------------|-----------------------------------|
| Relative Sensitivity: | 35/40 87.5% (95% CI: 68.6%-93.0%) |
| Relative Specificity: | 92/93 98.9% (95% CI: 94.2%-99.9%) |

Subject Demographics

| Age Group | No. of Subjects | Antigen Positive | Prevalence |
|---------------|-----------------|------------------|------------|
| ≤ 5 years | 0 | N/A | N/A |
| 6 – 21 years | 8 | 3 | 37.50% |
| 22 - 59 years | 96 | 25 | 26.04% |
| ≥ 60 years | 29 | 8 | 27.69% |
| Total | 133 | 36 | 27.07% |

Specimen Positivity by days post symptom onset

| Days post symptom onset | No. of Subjects | Antigen Positive | Prevalence |
|-------------------------|-----------------|------------------|------------|
| 1 | 4 | 1 | 25.00% |
| 2 | 59 | 15 | 25.42% |
| 3 | 44 | 14 | 31.82% |
| 4 | 9 | 2 | 22.22% |
| 5 | 4 | 0 | 0.00% |
| 6 | 11 | 4 | 36.36% |
| 7 | 2 | 0 | 0.00% |

Results

| | | RT-PCR | | Total |
|--------------|----------|----------|----------|-------|
| | | Positive | Negative | |
| Antigen Test | Results | | | |
| | Positive | 35 | 1 | 36 |
| | Negative | 5 | 92 | 97 |
| Total | | 40 | 93 | 133 |

CROSS-REACTIVITY

The following potentially cross-reactive microorganisms were tested with SARS-CoV-2 negative and spiked positive specimens at 3x LoD with inactivated SARS-CoV-2. All testing were performed with three different lots and tested in triplicate. The below listed organisms or viruses do not cross-react at the stated concentration.

| Potential Cross-Reactant | Concentration | Results | |
|-------------------------------------|--|-------------------|-------------------------------|
| | | Negative Specimen | Spiked with Positive Specimen |
| Human Coxsackievirus | 2.8×10 ⁵ TCID ₅₀ /ml | Negative | Positive |
| Mumps virus | 2.8×10 ⁶ TCID ₅₀ /ml | Negative | Positive |
| Haemophilus para-influenzae | 6×10 ⁶ bacteria/ml | Negative | Positive |
| Staphylococcus aureus | 6×10 ⁶ bacteria/ml | Negative | Positive |
| Neisseria meningitides | 10 ⁵ organisms/ml | Negative | Positive |
| Streptococcus sp. Group A | 10 ⁸ organisms/ml | Negative | Positive |
| Streptococcus sp. Group B | 6×10 ⁶ bacteria/ml | Negative | Positive |
| Streptococcus sp. Group C | 6×10 ⁶ bacteria/ml | Negative | Positive |
| Influenza A Virus H3N2 | CEID ₅₀ ≥10 ² per 0.2 ml | Negative | Positive |
| Adenovirus (e.g. C1 Ad. 71)-Type 7A | 7.05 x10 ⁴ TCID ₅₀ /ml | Negative | Positive |
| Enterovirus (e.g. EV68) | 1.67 x10 ⁵ TCID ₅₀ /ml | Negative | Positive |
| Human Metapneumovirus | 5.43 x10 ⁵ TCID ₅₀ /ml | Negative | Positive |
| Influenza A H1N1 (New Cal/20/99) | 1.64 x10 ⁶ TCID ₅₀ /ml | Negative | Positive |
| Influenza B (Florida/02/06) | 7.05 x10 ⁴ TCID ₅₀ /ml | Negative | Positive |
| Parainfluenza virus 1 | 1.30×10 ⁸ TCID ₅₀ /ml | Negative | Positive |
| Parainfluenza virus 2 | 1.64×10 ⁶ TCID ₅₀ /ml | Negative | Positive |
| Parainfluenza virus 3 | 9.44×10 ⁵ TCID ₅₀ /ml | Negative | Positive |
| Parainfluenza virus 4 | 4.03 x10 ⁶ TCID ₅₀ /ml | Negative | Positive |
| Respiratory syncytial virus-Type A | 5.43 x10 ⁵ TCID ₅₀ /ml | Negative | Positive |
| Rhinovirus (Type 1A) | 1.78 x10 ⁵ TCID ₅₀ /ml | Negative | Positive |
| Bordetella pertussis | 1.61 x10 ⁹ CFU/ml | Negative | Positive |

| | | | |
|--|--|----------|----------|
| Candida albicans | 8.96 x10 ⁷ CFU/ml | Negative | Positive |
| Haemophilus influenzae | 7.76 x10 ⁷ CFU/ml | Negative | Positive |
| Legionella pneumophila | 2.69 x10 ⁹ CFU/ml | Negative | Positive |
| Mycobacterium tuberculosis | 9.80 x10 ⁸ CFU/ml | Negative | Positive |
| Mycoplasma pneumoniae | 4.51 x10 ⁷ CCU/ml | Negative | Positive |
| Pneumocystis jirovecii (PJP)-S. cerevisiae Recombinant | 4.93 x10 ⁷ CFU/ml | Negative | Positive |
| Pseudomonas aeruginosa | 1.21 x10 ⁹ CFU/ml | Negative | Positive |
| Staphylococcus epidermis | 1.73 x10 ⁹ CFU/ml | Negative | Positive |
| Streptococcus pneumoniae | 3.23 x10 ⁸ CFU/ml | Negative | Positive |
| Streptococcus pyogenes | 2.34 x10 ⁸ CFU/ml | Negative | Positive |
| Streptococcus salivarius | 1.17 x10 ⁸ CFU/ml | Negative | Positive |
| Human coronavirus 229E | 2.09 x10 ⁵ TCID ₅₀ /ml | Negative | Positive |
| Human coronavirus OC43 | 1.50 x10 ⁵ TCID ₅₀ /ml | Negative | Positive |
| Human coronavirus NL63 | 8.50 x10 ⁴ TCID ₅₀ /ml | Negative | Positive |
| MERS-coronavirus | 4.51 x10 ⁵ TCID ₅₀ /ml | Negative | Positive |
| Chlamydomphila pneumoniae | 1.75 x10 ⁷ IFU/ml | Negative | Positive |

*in silico analysis using Protein BLAST indicates that homology between SARS-CoV-2 nucleocapsid protein and hCoV-HKU1 nucleocapsid protein is at 37% across 87% of the sequences, therefore, cross-reactivity **cannot** be ruled out.

*in silico analysis using Protein BLAST indicates that homology between SARS-CoV-2 nucleocapsid protein and SARS-CoV nucleocapsid protein is at 91% across 100% of the sequences, therefore, cross-reactivity **cannot** be ruled out.

INTERFERING SUBSTANCES

The following potentially interfering substances were added to SARS-CoV-2 negative and spiked positive specimens at 3x LoD. No substances showed any interference with the test.

| Whole Blood (4%) | Mucin (0.5%) |
|--|---|
| NeilMed NasoGEL (5% v/v) | Zicam Cold Remedy Nasal Spray (5% v/v) |
| Flonase nasal spray (5% v/v) | CVS Nasal Drops (Phenylephrine) (15% v/v) |
| Afrin Original (Oxymetazoline) (15% v/v) | NasalCrom Nasal Spray (15% v/v) |
| Chloraseptic (15% v/v) | Alkalol Nasal Wash (10% v/v) |
| Tobramycin (4 µg/mL) | Mupirocin (10 mg/mL) |
| Oseltamivir Phosphate (5 mg/mL) | |

HIGH DOSE HOOK EFFECT

The potential high-dose hook effect on the performance of the Sienna-Clarity COVID-19 Antigen Rapid Test Cassette was evaluated using positive inactivated virus culture. All testing were performed with three different lots and tested in triplicate. No hook effect was observed when tested at up to 1.0 x 10⁵ TCID₅₀/ml.

SPECIMEN STABILITY

The specimen stability of a nasopharyngeal swab specimen with the Sienna-Clarity COVID-19 Antigen Rapid Test Cassette was evaluated with SARS-CoV-2 negative and spiked positive specimens at 2x LoD. The stability at room temperature was evaluated by placing the samples in a dry tube and stored at 30°C, for up to 180 minutes; the stability at refrigerated temperature was evaluated by storing the samples at ~4°C, for up to 36 hours. No false results were obtained during the study.

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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.

Index of Symbols

| | | | | | |
|----------|-----------------------------|---------------------------------------|----------------------------------|----------|---------------------------------|
| V | For in vitro diagnostic use | H | Use by | D | Contents sufficient for n tests |
| h | Catalogue number | L | Do not use if package is damaged | Y | Do not re-use |
| g | Batch code | i | Consult instruction for use | p | Keep dry |
| M | Manufacturer | I <small>2°C 30°C</small> | Consult instruction for use | w | Protect from direct sunlight |
| N | Date of manufacture | X_n | Temperature limit at 2°C – 30°C. | C | CE Mark |

Manufactured By:

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 Email: info@salofa.com
 Web: www.salofa.com
 REF: CLA-COV19AG-VIS/ 102242
 Version 3 DRAFT, Mar 2023



US Technical Support Contact:

TECH SUPPORT: 1 -877- 485-7877
WWW.CLARITYDIAGNOSTICS.COM
covid19techsupport@claritydiagnostics.com

Quick User Guide

Sienna-Clarity COVID-19 Antigen Rapid Test Cassette

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

A rapid test for the qualitative detection of novel coronavirus SARS-CoV-2 antigen in nasopharyngeal swab.

Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals. You may need to purchase Additional tests may be needed to perform this serial (repeat) testing.

Please refer to the package insert for detailed assay instructions, cautions, limitations and warnings.

INTENDED USE

The Sienna-Clarity 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 6 days of symptom onset when tested twice over three days with at least 48 hours between tests.

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-Clarity 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, which 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 definitive cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

All negative results are 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 measures, such as isolating from others and wearing masks. Negative results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

The Sienna-Clarity COVID-19 Antigen Rapid Test Cassette is intended for use by healthcare professionals or operators who are proficient in performing tests in point of care settings. The Sienna-Clarity COVID-19 Antigen Rapid Test Cassette is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

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. Failure to follow the instructions may result in inaccurate test results.

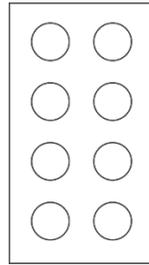
Materials required for testing



Extraction buffer tube



Sterile swab



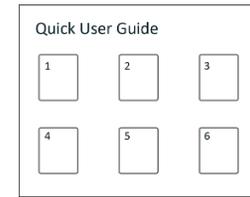
Workstation



Test cassette



Instruction for use



Quick User Guide



Timer

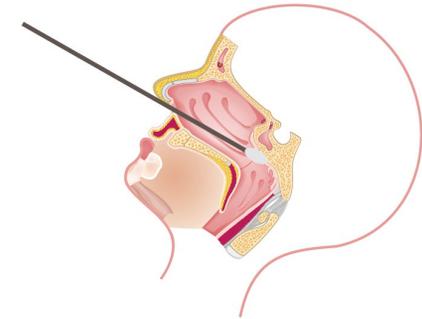


Gloves

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.

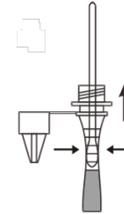
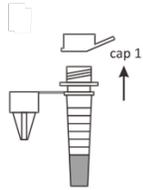


For more info, please visit: https://www.cdc.gov/coronavirus/2019-ncov/downloads/lab/NP_Specimen_Collection_Infographic_FINAL_508.pdf

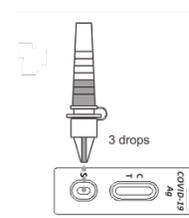
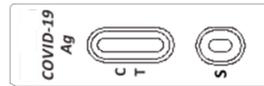
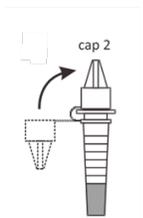
TEST PROCEDURE

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.

TEST INTERPRETATION

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results for COVID-19.

| Status on First Day of Testing | First Result Day 1 | Second Result Day 3 | Interpretation |
|--------------------------------|--------------------|---------------------|-----------------------|
| With Symptoms | Positive | N/A | Positive for COVID-19 |
| | Negative | Positive | Positive for COVID-19 |
| | Negative | Negative | Negative for COVID-19 |

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

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

COVID-19 Negative (-)

If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.

To increase the chance that the negative result for COVID-19 is accurate, you should:

- **Test again in 48 hours if you have symptoms on the first day of testing.**

A negative test result indicates that the virus that causes COVID-19 was not detected in your sample. A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR. If you test negative and continue to experience COVID-19-like symptoms, (e.g., fever, cough, and/or shortness of breath) you should seek follow up care with your health care provider.



Negative

COVID-19 Positive (+)

If the Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible reddish purple test (T) line with the control (C) line should be read as positive.

You do not need to perform repeat testing if you have a positive result at any time.

A positive test result means that the virus that causes COVID-19 was detected in your sample and it is very likely you have COVID-19 and are contagious. Please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).



Positive

Invalid

If the Control (C) line is not visible, the test is invalid. Re-test with a new swab and new test device.



Invalid

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.

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 “TEST INTERPRETATION”. If the correct control results are not obtained, do not perform patient testing or report patient results. Contact the US Technical Support at 1-877-485-7877/ covid19techsupport@claritydiagnostics.com or email info@salofa.com

ASSISTANCE

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

Email: info@salofa.com

OR

Email: covid19techsupport@claritydiagnostics.com/Tel: 1-877-485-7877 (US)

WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION

Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.

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.

Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.