SPERA™ COVID-19 AG TEST

Instructions for Use

Rapid Test for the Detection of SARS-CoV-2 Antigen

For use under the Emergency Use Authorization (EUA) only

For in vitro diagnostic use

For prescription use only

For use with kit provided nasal swabs

Intended Use

The SPERA COVID-19 Ag Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct anterior nasal swab specimens collected by a healthcare provider from individuals suspected of COVID-19 within the first 5 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, high or waived complexity 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 SPERA COVID-19 Ag Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in anterior nasal 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 patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Additional confirmatory testing with a molecular test for positive results may be necessary if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection. 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 SPERA COVID-19 Ag Test is intended for use by healthcare professionals or operators who are proficient in performing tests in point of care settings. The SPERA COVID-19 Ag Test 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 and Explanation of the Test

Coronaviruses are a large family of viruses which may cause illness in animals or humans. SARS-CoV-2 is an enveloped, single-stranded RNA virus of the genus. SARS-CoV-2, also known as the COVID-19 virus, was first identified in Wuhan, Hubei Province, China December 2019. The WHO declared that COVID-19 was a pandemic on March 11, 2020, and human infection has spread globally, with hundreds of thousands of confirmed infections and deaths.

The median incubation time is estimated to be 5.1 days with symptoms expected to be present within 12 days of infection. The symptoms of COVID-19 are similar to other viral respiratory diseases and include fever, cough and shortness of breath.

The SPERA™ COVID-19 Ag Test is a rapid lateral flow immunoassay for the qualitative detection of nucleocapsid protein antigen to SARS-CoV-2 in anterior nasal swab specimens directly placed in sample collection tube containing the extraction reagent buffer supplied in the test kit. The SPERA™ COVID-19 Ag Test is supplied with all components necessary to complete a test for SARS-CoV-2.

Principles of the Test

The SPERA™ COVID-19 Ag Test utilizes immunochromatographic technology that uses antibodies to detect SARS-CoV-2 nucleocapsid protein from anterior nasal swab specimens. Antibodies specific for SARS-CoV-2 as well as control antibodies are immobilized as two distinct lines on the nitrocellulose membrane.

The anterior nasal swab collected from the patient is placed into the sample collection tube to release the specimen containing viral particles from the swab. Three drops of the sample suspension solution are then added to the sample well on the test device. Results are visually interpreted 15 minutes following addition of sample to the device.

Reagents and Materials Provided

CONTENTS NAME	QUANTITY	DESCRIPTION
Individually packaged SPERA™ COVID-19 Ag Test Devices **REF: XH-100-110**	10	Anti-SARS-CoV-2 mouse monoclonal antibody immobilized on nitrocellulose membrane, and anti-SARS-CoV-2 mouse monoclonal antibody bonded latex dried in the pad
SPERA™ COVID-19 Ag Test Sample Collection Tubes **REF: XH-100-120**	0.4 mL per tube x 10 tubes x 5 tubes per bag x 2 bags	Sample collection tube with a buffer solution containing a surfactant and 0.08% (w/v) of sodium azide as a preservative
SPERA™ COVID-19 Ag Test Sample Collection Caps **REF: XH-100-130**	10	Filter tops for dropping sample suspension buffer containing suspended sample into the device
Sterile sample collection swabs **REF: XH-100-140**	10	Individually packaged sterile nasal swabs for specimen extraction
Sample tube stand	1	Disposable paperboard tube stand, assembly required before use
Package Insert	1	Instructions for use
Quick Reference Guide	1	Quick reference instructions

Reagents Materials Required, But Not Provided

CONTENTS NAME	QUANTITY REQUIRED	DESCRIPTION
Timer or stopwatch	1	Device to reliably keep track of time
SPERA™ COVID-19 Ag Test Positive Control Swab **REF: XH-100-200**	1 per new lot of kit or per new operator.	Swab coated with non-infectious recombinant SARS-CoV-2 nucleocapsid protein antigen. Purchase the SPERA™ COVID-19 Ag Positive Control Swab (REF: XH-100-200) by contacting: support@xtravahealth.com.
SPERA™ COVID-19 Ag Test Negative Control Swab **REF: XH-100-205**	1 per new lot of kit or per new operator	Sterile blank nasal swab Purchase the SPERA™ COVID-19 Ag Negative Control Swab (REF: XH-100-205) by contacting: support@xtravahealth.com.

Warnings and Precautions

- For in vitro diagnostic use
- For prescription use only
- For use with kit provided nasal swabs
- This product is authorized by FDA under an EUA for use by authorized laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C §263a, that meet the requirements to perform moderate, high, or waived complexity tests. This product is intended to be 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.
- 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 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.

- **Serial testing should be performed in symptomatic individuals with negative results at least twice over three days (with 48 hours between tests). You may need to purchase additional tests to perform this serial (repeat) testing.**
- Federal Law restricts this test to sale by or on the order of a licensed practitioner (U.S. only).
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- Laboratories within the United States and its territories are required to report all results to the appropriate public health laboratories.
- Do not use specimens stored in media other than SPERA COVID-19 Ag Specimen Buffer.
- Do not store or transport specimens in viral transport media.
- Treat all specimens as potentially infectious. Follow universal precautions when handling samples, this kit, and its contents.
- Use of nitrile or latex gloves is recommended for handling patient specimens.
- Do not use the kit contents beyond the expiration date.
- Do not store product in direct sunlight.
- Do not use product if it has been frozen.
- Leave the test device sealed within its foil pouch until just prior to use.
- Do not use a test device that appears damaged or has been dropped after opening
- Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
- To obtain accurate results, the Quick Reference Guide must be followed. The SPERA™ COVID-19 Ag Test Instructions for Use is available at www.xtravahealth.com/speraproduct-documentation.
- Do not use a nasal swab that is not provided with the kit.
- Do not transfer sample from the sample collection tube to the test device without the sample collection cap in place.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- Do not use if any of the test kit contents or packaging is damaged.
- Test components are single use. Do not re-use.

- Do not use kit past its expiration date.
- Do not touch the swab tip.
- Once opened, the test device should be used within 60 minutes.
- Dispose of used and unused kit contents as biohazardous waste according to federal, state, and local regulatory requirements.
- **Do not read test results before 15 minutes or after 30 minutes. Results read before 15 minutes or after 30 minutes may lead to a false positive, false negative, or invalid result.**
- **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. If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.**

Hazardous Ingredients in the Sample Buffer

CHEMICAL NAME/CAS	GHS CODE FOR EACH INGREDIENT	CONCENTRATION
Sodium Azide / 26628-22-8	Acute Tox. 2(Oral), H300 Acute Tox. 1 (Dermal), H310 MSDS: https://www.fishersci.com/store/msds?partNumber=S227I25&productDescription=SOD+AZIDE+GRAN+PURIF+25G+IND&vendorId=VN00033897&countryCode=US&language=en	0.08%

- For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

Kit Storage and Stability

The SPERA™ COVID-19 Ag Test kit should be stored at 2-30°C away from direct sunlight. Do not freeze. The SPERA™ COVID-19 Ag Test kit is stable until the expiration date printed on the outside of the outer packaging. If the kit is stored at less than 15°C, ensure all test components are placed at room temperature (15-30°C) at least 30 minutes prior to use. Do not open kit contents until immediately prior to use.

Quality Control

PROCEDURAL CONTROL

The SPERA™ COVID-19 Ag Test has a built-in procedural control contained within the test device. The blue line at the "control" position of the device will always appear if the sample flows properly and the reagents are working.

EXTERNAL POSITIVE AND NEGATIVE CONTROLS

The SPERA™ SARS-CoV-2 Positive Control Swab and Negative Control Swab are available to be provided separately. The external positive and negative controls will validate the entire test. External controls shall be evaluated:

- With every new operator
- Once with each new shipment received (provided that each different lot received in the shipment is tested)
- When problems with testing are suspected or identified
- As necessary to conform with local, state and/or federal regulations, accrediting requirements, or your lab's standard quality control procedures

If the blue control line does not appear or the correct results are not obtained with the external positive and/or negative controls, discard the test and repeat with new components. If the problem persists upon the repeat test, report the problem to Xtrava Health technical support at: 1-888-987-2821.

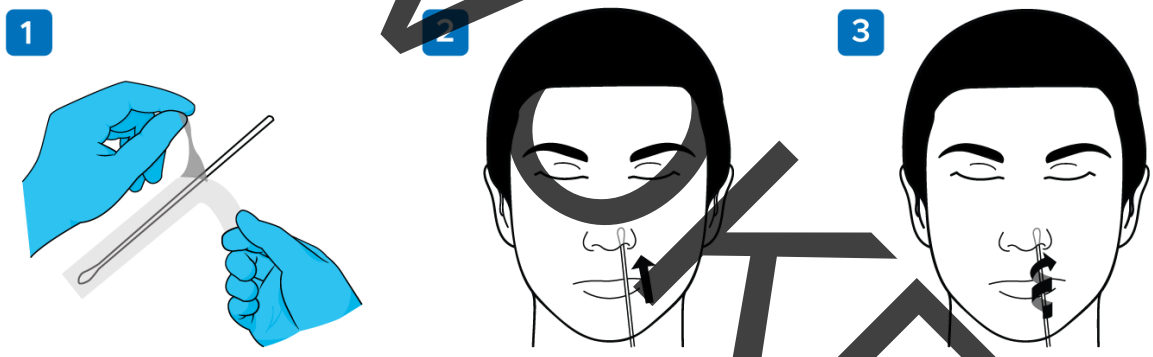
Specimen Collection and Handling

PREPARATION FOR SAMPLE COLLECTION

1. Determine the number of samples to be collected.
2. Prepare one sterile swab, one sample collection tube, one sample collection cap, and one test device for each patient sample to be collected. NOTE: If you notice the swab is damaged prior to use, discard the swab.
3. Use components immediately after opening.

SAMPLE COLLECTION

Collect the sample using the provided swab following the CDC guidelines https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html



Open

Remove the swab from the container, being careful not to touch the soft end with your hand.

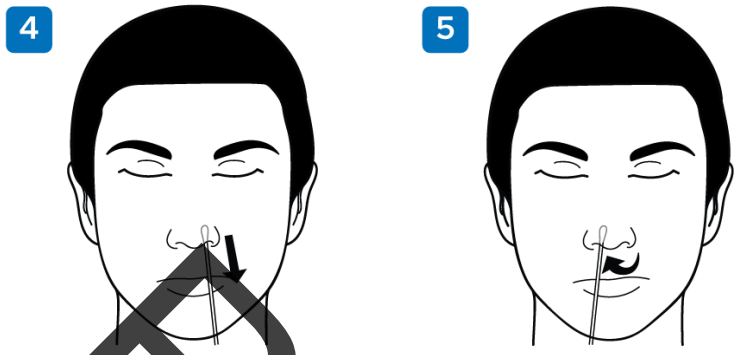
Insert the swab

Insert the entire collection tip of the swab provided (usually ½ to ¾ of an inch, or 1 to 1.5 cm) inside the nostril.

Collect Sample

Firmly sample the nasal wall by rotating the swab in a circular path against the nasal wall at least 4 times.

Take approximately 15 seconds to collect the specimen. Be sure to collect any nasal drainage that may be present on the swab.



Remove swab

Gently remove the swab.

Repeat

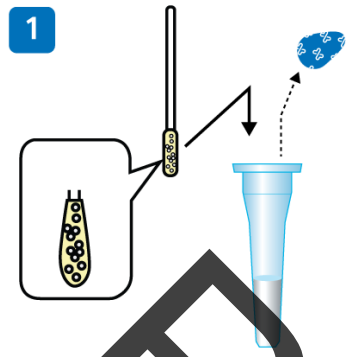
Repeat in the other nostril using the same swab.

SPECIMEN TRANSPORT AND STORAGE

Specimens collected for the SPERA™ COVID-19 Ag Test should be tested as soon as possible and should not be stored or transported. The sample is stable for up to 60 minutes after preparation. Testing collected specimen after 60 minutes could yield false results.

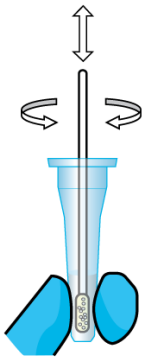
Test Procedure

SAMPLE PREPARATION:



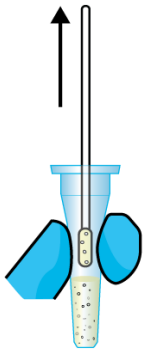
Dip Swab

Remove the aluminum seal from the sample collection tube. Immerse the swab containing the collected sample into the liquid in the sample collection tube.



Mix

Pinch the tip of the swab from the outside of the tube. Continue to pinch the outside of the tube to release the sample from the swab by moving the swab up and down while rotating. Continue the process for 15 seconds.

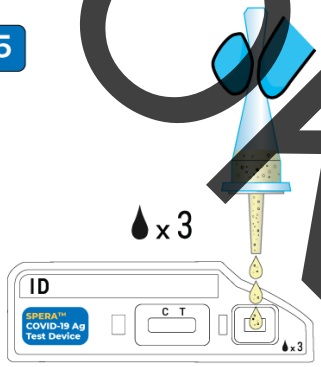


Remove Swab

Pinch the outside of the tube above the tip at the top of the tube and pull out the swab (while squeezing the tube) to remove any remaining sample and suspension solution from the swab.

Attach Cap

Securely attach the sample collection cap to the collection tube containing the sample.



Add Sample

Slowly turn it vertically upside down, pinch the tube, and add 3 drops to the sample well on the test device. The first drop may contain bubbles, but this will not affect the test results.

Note: Fewer than three drops may result in false negative results.

IMPORTANT

Once the sample has been applied to the sample well, allow the test device to sit undisturbed stand at 15-30°C for 15 minutes on a level surface, then interpret results. Do not read results if more than 30 minutes after applying the sample to the test device have elapsed.

Note: Interpretation of the test before 15 minutes or after 30 minutes could yield false results. Do not interpret the test before 15 minutes or past 30 minutes.

NOTE: Upon completion of the test, discard all materials as biohazardous waste according to federal, state, and local regulations.

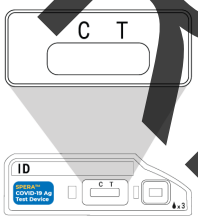
INTERPRETATION OF RESULTS

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

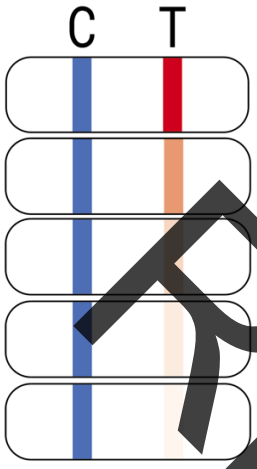
	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative for COVID-19

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



Read Test Device

POSITIVE RESULT



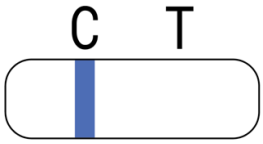
If the Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible test (T) line with the control line (C) should be read as positive.

Note: 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.

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 [Test Name] 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 (a false positive).

NEGATIVE RESULT



If only the blue control line under the letter "C" and no red test line under the letter "T" appears by the end of the 15-minute time frame, the sample is considered negative and results are valid.

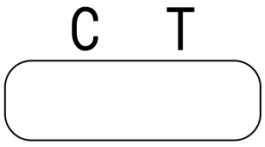
Note: To increase the chance that the negative result for COVID-19 is accurate, you should:

- **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.

INVALID RESULT



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

Limitations

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between 06/04/2021 and 07/22/2021. 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 SARSCoV-2 and their prevalence, which change over time.
- 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.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. 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.
- 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.
- 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.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and you likely have COVID-19.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.

Conditions for Intended Authorization

The SPERA™ COVID-19 Ag Test Letter of Authorization[1], along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling will be available on the FDA website post authorization: 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 in using the SPERA™ COVID-19 Ag Test, the relevant Conditions of Intended Authorization are listed below:

A. Authorized laboratories using your product must include with the 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 the 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 the product are not permitted.

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

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 SPERA™ Customer Support (support@xtravahealth.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which they become aware.

[1] The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meets the 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 a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation." as "authorized laboratories."

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 authorized labeling.

G. SPERA™ COVID-19 Ag, authorized distributors, and authorized laboratories using your product will 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.

Clinical Performance

The clinical performance characteristics of the SPERA™ COVID-19 Ag Test were evaluated in a multi-site prospective study in the U.S. in which patients were sequentially enrolled and tested between June 4, and July 22, 2021.

The performance of the SPERA™ COVID-19 Ag Test was established with nasal swabs collected from individual symptomatic patients (within 5 days of onset) who were suspected of COVID-19. The study was conducted at three (3) point of care (POC) sites in U.S. by 14 test operators. No training on the use of the test was provided to the operators. Operators used the Quick Reference Guide to perform testing. There were 337 subjects of the 342 total enrolled subjects (98.5%) that were determined to be eligible per the protocol (for the primary objective). A total of 337 eligible subjects were enrolled of which 49 (14.5%) were COVID positive and 288 (85.4%) were COVID negative by the comparator test. Test results were compared to the results from a highly sensitive EUA approved COVID-19 RT-PCR test.

External control testing, using the SPERA™ COVID-19 Ag Test Positive and Negative Controls, was performed prior to sample testing each day, at all study sites.

The agreement between the SPERA™ COVID-19 Ag Test and the RT-PCR comparator method are presented in the table below.

Table 1. SPERA™ COVID-19 Ag Test Performance Against Comparator Method

SPERA™ COVID-19 AG TEST	RT-PCR COMPARATOR METHOD		
	POSITIVE	NEGATIVE	TOTAL
Positive	45	9[2]	54
Negative	4	279	283
Total	49	288	337
Positive Percent Agreement (PPA)	(45/49) x 100% = 91.8% (95% CI: 80.4 to 97.7%)		
Negative Percent Agreement: (NPA)	(279/288) x 100 = 96.9% (95% CI: 94.2 to 98.6%)		

[2] Following discordant analysis two false negative samples were confirmed as positive samples.

Patient Demographics

Patient demographics (gender, age, time elapsed since onset of symptoms) are available for the 337 samples used in the analysis. The table below shows the positive results stratified by patient age for the SPERA™ COVID-19 Ag Test.

Table 2. SPERA™ COVID-19 Ag Test Positive Results by Age Group

AGE	COMPARATOR POSITIVE	COMPARATOR NEGATIVE	SUM	% POSITIVITY RATE
5 to 21 years	6	29	35	17.1
22 to 59 years	30	195	225	13.3
≥ 60	13	64	77	16.9
Sum	49	288	337	14.5

TABLE 3. POSITIVE RESULTS STRATIFIED BY DAYS POST-SYMPTOM ONSET

DAYS POST SYMPTOM ONSET	# SPECIMENS TESTED	# POSITIVE SPECIMENS	COMPARATOR POSITIVE
0	29	2	2
1	100	8	8
2	86	10	9

3	71	17	15
4	41	15	13
5	10	2	2
Total	**337**	**54**	**49**

Additional Clinical Performance

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 SARSCoV-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 RTPCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection.

Performance of the antigen test with serial testing in individuals is described in Table 4.

Table 4: 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 POSITIVE PCR 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%)

DAYS AFTER FIRST POSITIVE PCR TEST RESULT	SYMPTOMATIC ON FIRST DAY OF TESTING AG POSITIVE / PCR POSITIVE (ANTIGEN TEST PERFORMANCE % PPA)		
	1 TEST	2 TESTS	3 TESTS
10	4/9 (44.4%)	3/7 (42.9%)	

Analytical Performance

Limit of Detection (LOD) – Analytical Sensitivity

The limit of detection for the SPERA™ COVID-19 Ag Test was determined by using 125µL radiation-inactivated SARS-CoV-2 (isolate USA-WA1/2020) spiked onto sterile nasal swabs. A preliminary LoD was determined by first testing serial two-fold dilutions of gamma irradiated SARS-CoV-2 (isolate USA-WA1/2020) stock diluted in pooled negative nasal matrix (PNM) in triplicate which was further confirmed by an additional 20 replicates. *Based upon the testing procedure for this study the LoD of* 1.56 x 10^3 *$TCID_{50}$/mL equates to 195 $TCID_{50}$/swab.*

Table 5. LoD of the SPERA™ COVID-19 Ag Test

VIRUS CONCENTRATION ($TCID_{50}$/ML)	NUMBER OF POSITIVE/TOTAL	% DETECTED
1.56 x 10^3	20/20	100%

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. Specimen pools were prepared by the RADx® team using clinical pooled samples from currently circulating Omicron strains 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 test detected 100% of live virus Omicron samples at a Ct-value of 21.6 (n=5). Testing was also compared to two additional EUA-authorized OTC antigen tests (Assay #1 and Assay #2). Omicron dilutions at lower viral concentrations (Ct-values greater than 21.6) were not detected by this test in this study.

Omicron Pool 1 - Live Omicron Clinical Samples	Average N2 Ct (n=9)	Assay #1 Percent Positive (n = 5)	Assay #2 Percent Positive (n = 5)	SPERA COVID-19 Ag Test Percent Positive (n=5)
Dilution 1	**19.4**	100	100	100
Dilution 2	**20.6**	100	100	100
Dilution 3	**21.6**	100	100	100
Dilution 4	**22.4**	100	100	0
Dilution 5	**23.3**	100	100	0
Dilution 6	**24.5**	100	0	0

Dilution 7	**25.6**	100	0	0
Dilution 8	**26.5**	0	0	0
Dilution 9	**27.7**	0	0	0
Dilution 10	**28.5**	0	0	0
Dilution 11	**29.4**	0	0	0
Dilution 12	**30.3**	0	0	0

CROSS-REACTIVITY (ANALYTICAL SPECIFICITY) AND MICROBIAL INTERFERENCE

Analytical specificity of the SPERA™ COVID-19 Ag Test was evaluated with a panel of sixteen (16) viruses, ten (10) bacteria, three (3) fungi, and pooled nasal wash. Final target organism concentrations were tested at ≥ 1.43×10^5 $TCID_{50}$/mL, 1.0×10^5 PFU/mL, or 1.43×10^5 $CEID_{50}$/mL for viruses, and ≥ 1.0×10^6 cfu/mL for bacteria and fungi.

The microbial interference was performed with the same panel of microorganisms at the same concentrations in the samples that were spiked with SARS-CoV-2 at 3X LoD. The samples were tested in triplicates for both cross-reactivity and interference studies. No cross-reactivity and no microbial interference were observed. The results for cross-reactivity and microbial interference are presented in the table below.

TABLE 6. CROSS- REACTIVITY AND MICROBIAL INTERFERENCE TESTING OF THE SPERA™ COVID-19 AG TEST

PATHOGEN	CROSS REACTIVITY RESULTS	MICROBIAL INTERFERENCE RESULTS
Human coronavirus 229E	No Cross- Reactivity	No Interference
Human coronavirus OC43	No Cross- Reactivity	No Interference
Human coronavirus NL63	No Cross- Reactivity	No Interference
SARS-coronavirus	Cross- Reactivity	Interference
MERS-coronavirus	No Cross- Reactivity	No Interference
Adenovirus	No Cross- Reactivity	No Interference
Human metapneumovirus 4 Type B2	No Cross- Reactivity	No Interference
Parainfluenza virus 1	No Cross- Reactivity	No Interference
Parainfluenza virus 2	No Cross- Reactivity	No Interference
Parainfluenza virus 3	No Cross- Reactivity	No Interference
Parainfluenza virus 4b	No Cross- Reactivity	No Interference
Influenza A	No Cross- Reactivity	No Interference
Influenza B	No Cross- Reactivity	No Interference

PATHOGEN	CROSS REACTIVITY RESULTS	MICROBIAL INTERFERENCE RESULTS
Enterovirus 68	No Cross- Reactivity	No Interference
Respiratory syncytial virus	No Cross- Reactivity	No Interference
Rhinovirus	No Cross- Reactivity	No Interference
Haemophilus influenzae	No Cross- Reactivity	No Interference
Streptococcus pneumonia	No Cross- Reactivity	No Interference
Streptococcus pyogenes	No Cross- Reactivity	No Interference
Candida albicans	No Cross- Reactivity	No Interference
Bordetella pertussis	No Cross- Reactivity	No Interference
Mycoplasma pneumonia	No Cross- Reactivity	No Interference
Chlamydia pneumoniae	No Cross- Reactivity	No Interference
Legionella pneumophila	No Cross- Reactivity	No Interference
Mycobacterium tuberculosis	No Cross- Reactivity	No Interference
Pneumocystis carinii	No Cross- Reactivity	No Interference
P. jiroveci-S. cerevisiae	No Cross- Reactivity	No Interference

PATHOGEN	CROSS REACTIVITY RESULTS	MICROBIAL INTERFERENCE RESULTS
Staphylococcus aureus subsp. aureus	No Cross- Reactivity	No Interference
Staphylococcus epideermidis	No Cross- Reactivity	No Interference
Pooled Negative Matrix	Negative	Positive

High Dose Hook Effect

A hook effect study was completed with inactivated SARS-CoV-2 by spiking the highest concentration possible (concentration 2.8x106 TCID50 / ml) of SARS-CoV-2 onto swabs in triplicate and processing the replicates according to the Instructions for Use. No high dose Hook Effect was observed.

Table 7. Hook Effect Test Results

TEST CONCENTRATION $TCID_{50}$/ML	REPLICATES	POSITIVE RESULTS
2.80E+06	3	3/3

Endogenous Interfering Substances

The SPERA™ COVID-19 Ag Test was evaluated for performance in the presence of potentially interfering substances that might be present in a respiratory specimen. Negative specimens were evaluated in triplicate to confirm that the substances were not cross-reactive with the test. Specimens containing SARS-CoV-2 at a concentration near the limit of detection were also evaluated in the presence of the substances in triplicate to confirm that SARS-CoV-2 could still be detected. There was no interference observed for any of the tested substances (Table 7).

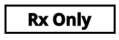
TABLE 8. INTERFERING SUBSTANCES TESTING OF THE SPERA™ COVID-19 AG TEST

INTERFERING SUBSTANCE	CONCENTRATION	NUMBER POS / # TESTED WITH UNSPIKED	NUMBER POS / # TESTED WITH VIRUS SPIKED
Human Whole Blood (EDTA tube)	4% v/v	(0/3)	(3/3)
Mucin (porcine stomach, type II)	0.5%	(0/3)	(3/3)
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	(0/3)	(3/3)
Naso GEL (NeilMed)	5% v/v	(0/3)	(3/3)
Nasal Drops (Phenylephrine)	15% v/v	(0/3)	(3/3)
Nasal Spray (Oxymetazoline)	15% v/v	(0/3)	(3/3)

Nasal Spray (Cromolyn)	15% v/v	(0/3)	(3/3)
Zicam	5% v/v	(0/3)	(3/3)
Homeopathic (Alkalol)	10% v/v	(0/3)	(3/3)
Sore Throat Phenol Spray	15% v/v	(0/3)	(3/3)
Tobramycin	4 pg/mL	(0/3)	(3/3)
Mupirocin	10 mg/mL	(0/3)	(3/3)
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	(0/3)	(3/3)
Fluticasone Propionate	5% v/v	(0/3)	(3/3)

SYMBOL GLOSSARY

IVD	In vitro diagnostic medical device	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device
	Manufacturer	Indicates the medical device manufacturer

	Use by	Indicates the date after which the medical device is not to be used
	Batch code	Indicates the manufacturer's batch code to identify the batch or lot
	Catalog number	Indicates the manufacturer's catalogue number to identify the medical device
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed
	Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information
	Prescription use only	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner
	Contains sodium azide	Contains sodium azide, toxic hazard addressed in the SDS document
	Consult instructions for use	Indicates the need for the user to consult the instructions for use

	Keep Away from Sunlight	Indicates a medical device that needs protection from light sources.
	Do Not Use if Package is Damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	Sterilized Using Irradiation	Indicates a medical device that has been sterilized using irradiation.

ORDERING AND CONTACT INFORMATION

Manufactured for:

Xtrava Inc., DBA Xtrava Health

3080 Olcott St. C201, Santa Clara CA 95054

1-888-987-2821

support@xtravahealth.com

www.xtravahealth.com

Xtrava Health

SPERA™ COVID-19 Ag Test

Quick Reference Guide

Rapid Test for the Detection of SARS CoV 2 Antigen

For use under the Emergency Use Authorization (EUA) only

For in vitro diagnostic use

For prescription use only

For use with nasal swabs provided in the kit

Intended Use

The SPERA™ COVID-19 Ag Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct anterior nasal swab specimens collected by a healthcare provider from individuals suspected of COVID-19 within the first 5 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, high or waived complexity 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 SPERA COVID-19 Ag Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in anterior nasal 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 patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Additional confirmatory testing with a molecular test for positive results may be necessary if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection. 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 SPERA COVID-19 Ag Test is intended for use by healthcare professionals or operators who are proficient in performing tests in point of care settings. The SPERA COVID-19 Ag Test 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.

Quality Control

PROCEDURAL CONTROL

The SPERA™ COVID-19 Ag Test has a built-in procedural control contained within the test device. The blue line at the "control" position of the device will always appear if the sample flows properly and the reagents are working.

EXTERNAL POSITIVE AND NEGATIVE CONTROLS

The SPERA™ SARS-CoV-2 Positive Control Swab and Negative Control Swab are available to be provided separately. The external positive and negative controls will validate the entire test. External controls shall be evaluated:

- With every new operator
- Once with each new shipment received (provided that each different lot received in the
- shipment is tested)
- When problems with testing are suspected or identified
- As necessary to conform with local, state and/or federal regulations, accrediting requirements, or your lab's standard quality control procedures

If the blue control line does not appear or the correct results are not obtained with the external positive and/or negative controls then discard the test and repeat with new components. If the problem persists upon the repeat test, report the problem to Xtrava Health technical support at : 1-888-987-2821.

EXTERNAL CONTROL TESTING PROCEDURES

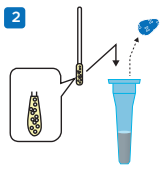
⚠ Contains Sodium Azide ⚠ Do not use if seal is broken

1

OPEN

Remove the Positive/Negative Control swab from the container, being careful not to touch the soft end with your hand.

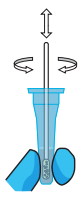
2



DIP SWAB

Remove the aluminum seal from the sample collection tube. Immerse the control swab into the liquid in the sample collection tube.

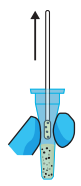
3



MIX

Pinch the tip of the swab from the outside of the tube. Continue to pinch the outside of the tube to release the sample from the swab by moving the swab up and down while rotating. Continue the process for 15 seconds.

4



REMOVE SWAB

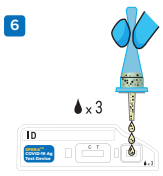
Pinch the outside of the tube above the tip at the top of the tube and pull out the swab (while squeezing the tube) to remove any remaining sample and suspension solution from the swab. The sample is stable for up to 60 minutes after preparation.

5

ATTACH CAP

Securely attach the sample collection cap to the collection tube containing the sample.

6



ADD SAMPLE

Slowly turn it vertically upside down, pinch the tube, and add 3 drops to the sample well on the test device. The first drop may contain bubbles, but this will not affect the test results.

Repeat steps 1 - 6 for the second control swab.

NOTE: Upon completion of the test, discard all materials as biohazardous waste according to federal, state and local regulations.

IMPORTANT

Once the sample has been applied to the sample well, allow the test device to sit undisturbed at 15-30°C for 15 minutes on a level surface, then interpret results. Do not read results if more than 30 minutes after applying the sample to the test device have elapsed.

For interpretation of results, refer to the section Interpretation of Results in this Quick Reference Guide

SPECIMEN TRANSPORT AND STORAGE

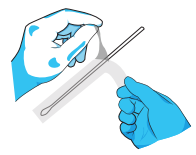
Specimens collected for the SPERA™ COVID-19 Ag Test should be tested as soon as possible and should not be stored or transported. The sample is stable for up to 60 minutes after preparation. Testing collected specimen after 60 minutes could yield false results.

Warnings

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.**

Specimen Collection Procedure

1



OPEN

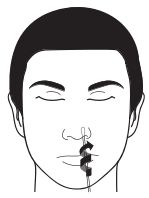
Remove the swab from the container, being careful not to touch the soft end with your hand.

2

INSERT SWAB

Insert the entire collection tip of the swab provided (usually ½ to ¾ of an inch, or 1 to 1.5 cm) inside the nostril.

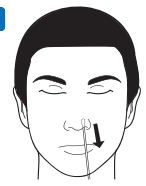
3



COLLECT SAMPLE

Firmly sample the nasal wall by rotating the swab in a circular path against the nasal wall at least 4 times. Take approximately 15 seconds to collect the specimen. Be sure to collect any nasal drainage that may be present on the swab.

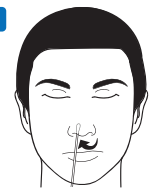
4



REMOVE SWAB

Gently remove the swab.

5



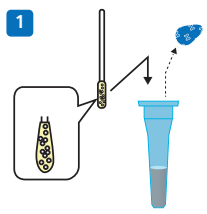
REPEAT

Repeat in the other nostril using the same swab.

Test Procedure

⚠ Contains Sodium Azide ⚠ Do not use if seal is broken

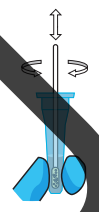
1



DIP SWAB

Remove the aluminum top from the sample collection tube. Next, immerse the swab containing the collected sample into the liquid in the sample collection tube

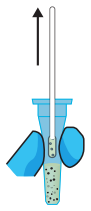
2



MIX WELL

Pinch the tip of the swab from the outside of the tube and move swab up and down while rotating to release the sample. Continue the process for 15 seconds.

3



REMOVE SWAB

Pinch and squeeze the top of the tube and pull out the swab (while squeezing the tube) to remove any remaining sample and suspension solution from the swab.

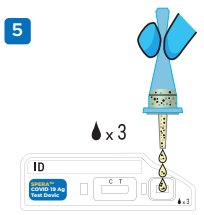
4

ATTACH CAP

Securely attach the sample collection cap to tube. The sample is stable for up to 60 minutes after preparation.

Discard the swab as biohazard waste.

5



ADD SAMPLE

Slowly pinch and turn the sample collection tube vertically upside down and add 3 drops to the sample well on the test device. The first drop may contain bubbles, but it will not affect the results.

Note: Fewer than three drops may result in false negative results.

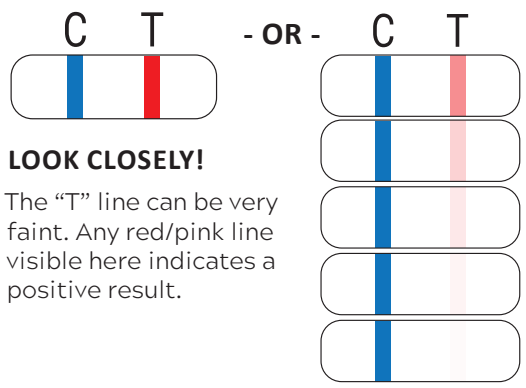
Interpretation of Results

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.

POSITIVE



LOOK CLOSELY!

The "T" line can be very faint. Any red/pink line visible here indicates a positive result.

If a red "T" test line and a blue "C" control line are visible at or before 15 minutes, the test is positive and the result is valid.

Note: 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.

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 SPERA™ COVID-19 Ag Test 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 (a false positive).

NEGATIVE RESULT

If only the blue control line under the letter "C" and no red test line under the letter "T" appears by the end of the 15-minute time frame, the sample is considered negative and results are valid.

Note: 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.

INVALID RESULT

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

IMPORTANT

- Once the sample has been applied to the sample well, allow the test device to sit undisturbed stand at 15-30°C for 15 minutes on a level surface, then interpret results. Do not read results if more than 30 minutes after applying the sample to the test device have elapsed.
- Note: Interpretation of the test before 15 minutes or after 30 minutes could yield false results. Do not interpret the test before 15 minutes or past 30 minutes.

ORDERING AND CONTACT INFORMATION

Technical Support
Contact us at 1-888-987-2821 or email us at support@xtravahealth.com

Manufactured for:
Xtrava Inc., DBA Xtrava Health
3080 Olcott St. C201, Santa Clara CA 95054
1-888-987-2821
support@xtravahealth.com
www.xtravahealth.com

Xtrava Health

SPERA™ COVID-19 Ag Test External Quality Control

Instructions For Use

For Use with SPERA™ COVID 19 Ag Test

For Use under the Emergency Use Authorization (EUA) only

For in vitro diagnostic use

For prescription use only

Warnings and Precautions

- For *in vitro* diagnostic use.
- Do not use controls in media other than SPERA™ COVID-19 Ag Specimen Buffer.
- Use of nitrile or latex gloves is recommended for handling controls.
- Do not use the controls beyond the expiration date.
- Do not store product in direct sunlight.
- Do not use product if it has been frozen.
- This product is for single use only. Do not re-use.
- Do not transfer sample from the sample collection tube to the test device without the sample collection cap in place.
- Interpretation of the test before 15 minutes or after 30 minutes could yield false results. Do not interpret the test before 15 minutes or past 30 minutes.
- Reagents contain sodium azide, which is harmful if inhaled, swallowed, or exposed to skin. Contact with acids produces a very toxic gas. If there is contact with skin, wash immediately with plenty of water. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up.
- Dispose of used and unused kit contents as biohazardous waste according to federal, state, and local regulatory requirements.
- Wear appropriate personal protective equipment (i.e. clothing, gloves, eye/face protection) when handing the contents of this kit.

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.**

Reagents and Materials Provided

Contents Name	Quantity	Description
SPERA™ COVID-19 Ag Test Positive Control Swab **REF: XH-100-200**	1	Swab coated with non-infectious recombinant SARS-CoV-2 nucleocapsid protein antigen. Purchase the SPERA™ COVID-19 Ag Positive Control Swab (REF: XH-100-200) by contacting support@xtravahealth.com
SPERA™ COVID-19 Ag Test Negative Control Swab **REF: XH-100-205**	1	Sterile blank nasal swab Purchase the SPERA™ COVID-19 Ag Negative Control Swab (REF: XH-100-205) by contacting: support@xtravahealth.com.
Package Insert	1	Instructions for use

Reagents Materials Required, But Not Provided

Contents Name	Quantity Required	Description
Timer or stopwatch	1	Device to reliably keep track of time

Storage and Stability

The SPERA™ SARS-CoV-2 Positive Control Swab and Negative Control Swab should be stored at 2-30°C away from direct sunlight. Do not freeze. The SPERA™ SARS-CoV-2 Positive Control Swab and Negative Control Swab is stable until the expiration date printed on the outside of the outer packaging, which is currently 3 months from the date of manufacture.

Quality Control

PROCEDURAL CONTROL

The SPERA™ COVID-19 Ag Test has a built-in procedural control contained within the test device. The blue line at the "control" position of the device will always appear if the sample flows properly and the reagents are working.

EXTERNAL POSITIVE AND NEGATIVE CONTROLS

The SPERA™ SARS-CoV-2 Positive Control Swab and Negative Control Swab are available to be provided separately. The external positive and negative controls will validate the entire test. External controls shall be evaluated:

- With every new operator
- Once with each new shipment received (provided that each different lot received in the shipment is tested)
- When problems with testing are suspected or identified
- As necessary to conform with local, state and/or federal regulations, accrediting requirements, or your lab's standard quality control procedures

If the blue control line does not appear or the correct results are not obtained with the external positive and/or negative controls then discard the test and repeat with new components. If the problem persists upon the repeat test, report the problem to Xtrava Health technical support at : 1-888-987-2821.

ORDERING AND CONTACT INFORMATION

Technical Support

Contact us at 1-888-987-2821 or email us at support@xtravahealth.com

Manufactured for:
Xtrava Inc., DBA Xtrava Health
3080 Olcott St. C201, Santa Clara CA 95054
1-888-987-2821
support@xtravahealth.com
www.xtravahealth.com

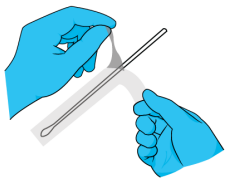
Quality Control Procedure

⚠ Contains Sodium Azide ⚠ Do not use if seal is broken

Thoroughly review the SPERA™ COVID-19 Ag Test Instructions for Use, including the warnings and limitations, before using this this External Quality Control document. The Instructions for Use are available at: www.xtravahealth.com/spera-product-documentation.

External Control Testing Procedures

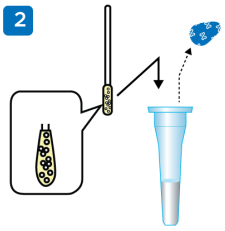
1



OPEN

Remove the Positive/Negative Control swab from the container, being careful not to touch the soft end with your hand.

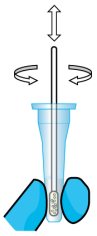
2



DIP SWAB

Remove the aluminum seal from the sample collection tube. Immerse the control swab into the liquid in the sample collection tube.

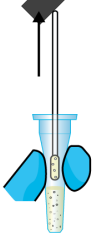
3



MIX

Pinch the tip of the swab from the outside of the tube. Continue to pinch the outside of the tube to release the sample from the swab by moving the swab up and down while rotating. Continue the process for 15 seconds.

4



REMOVE SWAB

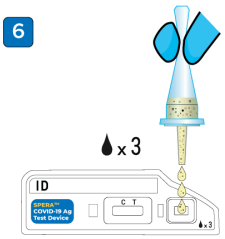
Pinch the outside of the tube above the tip at the top of the tube and pull out the swab (while squeezing the tube) to remove any remaining sample and suspension solution from the swab. The sample is stable for up to 60 minutes after preparation.

5

ATTACH CAP

Securely attach the sample collection cap to the collection tube containing the sample.

6



ADD SAMPLE

Slowly turn it vertically upside down, pinch the tube, and add 3 drops to the sample well on the test device. The first drop may contain bubbles, but this will not affect the test results.

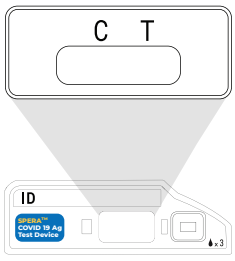
Repeat steps 1 - 6 for the second control swab.

NOTE: Upon completion of the test, discard all materials as biohazardous waste according to federal, state and local regulations.

IMPORTANT

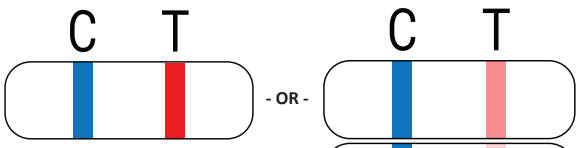
Once the sample has been applied to the sample well, allow the test device to sit undisturbed stand at 15-30°C for 15 minutes on a level surface, then interpret results. Do not read results if more than 30 minutes after applying the sample to the test device have elapsed.

Interpretation of Results



Read Test Device

POSITIVE RESULT

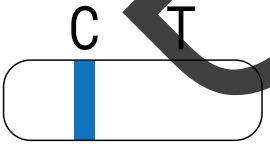


If a red "T" test line and a blue "C" control line are visible at or before 15 minutes, the test is positive and the result is valid.

Note: SPERA™ COVID-19 Ag Test Positive Control Swab should provide a positive result.

LOOK CLOSELY!
The "T" line can be very faint. Any red/pink line visible here indicates a positive result.

NEGATIVE RESULT



If only the blue control line under the letter "C" and no red test line under the letter "T" appears by the end of the 15-minute time frame, the sample is considered negative and results are valid.

Note: SPERA™ COVID-19 Ag Test Negative Control Swab should provide a negative result.

INVALID RESULT

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