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 only

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 swabs from individuals suspected of COVID-19 by their healthcare provider within the first five (5) days of symptom onset. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C §263a, that meet the requirements to perform moderate, 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 or SARS-CoV-2 viruses.

Results are for the identification of SARS-CoV-2 nucleocapsid protein. Antigen is generally detectable in anterior nasal swabs 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. 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 definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

Negative results should be treated as presumptive and may be confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's respiratory 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 medical professionals or operators who are proficient in performing tests in point of care settings. The SPERA™ COVID-19 Ag Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

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

In the USA, the emergency use of 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 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.

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 diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless declaration is terminated or the authorization is revoked sooner.

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

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

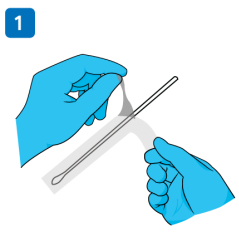
The SPERA™ SARS-CoV-2 Positive Control Swab and Negative Control Swab are available to be provided separately. The external positive and negative controls will validate the entire test. External controls shall be evaluated:

- 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.

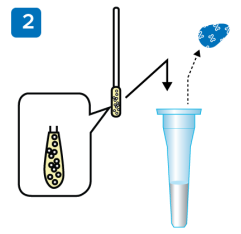
EXTERNAL CONTROL TESTING PROCEDURES

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



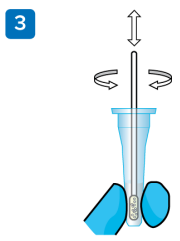
OPEN

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



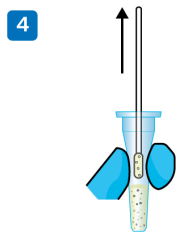
DIP SWAB

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



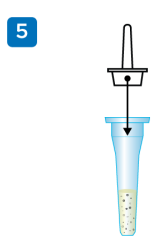
MIX

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.



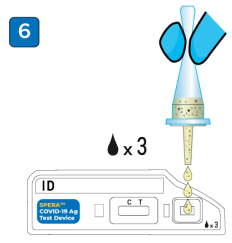
REMOVE SWAB

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. The sample is stable for up to 60 minutes after preparation.



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.

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.

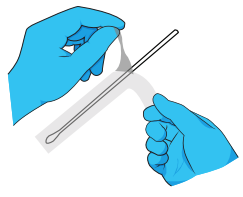
IMPORTANT

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 Collection Procedure

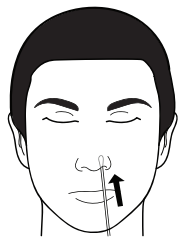
1



OPEN

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

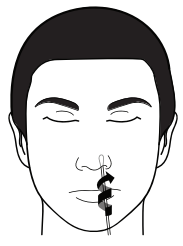
2



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.

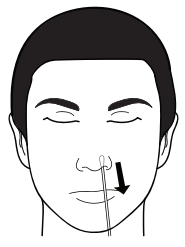
3



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.

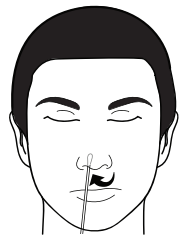
4



REMOVE SWAB

Gently remove the swab.

5



REPEAT

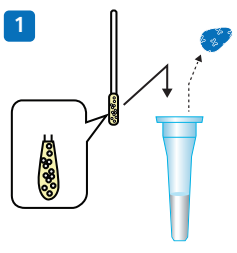
Repeat in the other nostril using the same swab.

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

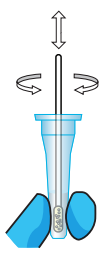
1



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

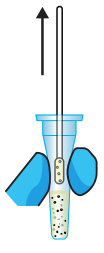
2



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.

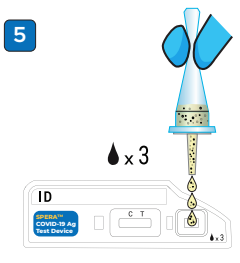
4

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

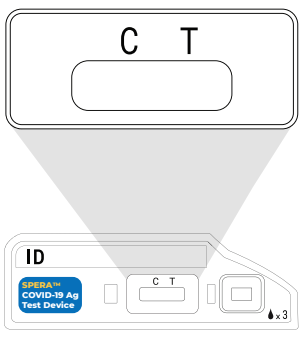
Slowly pinch and turn the sample collection tube vertically upside down and add 3 drops to the sample well on the test device. The first drop may contain bubbles, but it will not affect the results.

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

IMPORTANT

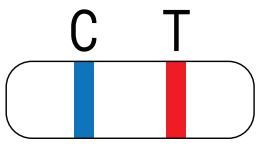
- Once the sample has been applied to the sample well, allow the test device to sit undisturbed stand at 15-30°C for 15 minutes on a level surface, then interpret results. Do not read results if more than 30 minutes after applying the sample to the test device have elapsed.
- Note: Interpretation of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

Interpretation of Results

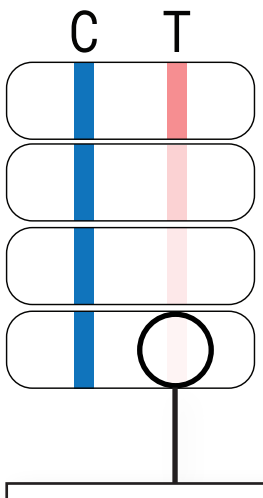


Read Test Device

POSITIVE RESULT



- OR -



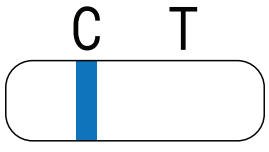
If a red “T” test line and a blue “C” control line are visible at or before 15 minutes, the test is positive and the result is valid.

Note: Additional confirmatory testing with a molecular test for positive results may also 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.

LOOK CLOSELY!

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

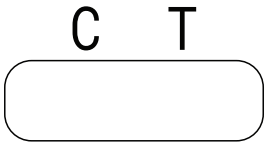
NEGATIVE RESULT



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: Negative results should be treated as presumptive and may be confirmed with a molecular assay, if necessary, for patient management.

INVALID RESULT



If a blue control line does not appear under the letter “C” by the end of the 15-minute time frame, regardless of the status of the red test line under the letter “T”, the test is invalid. Discard test materials and repeat the test.