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 only

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.

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.

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

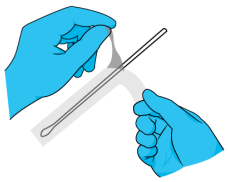
Quality Control Procedure

⚠ 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

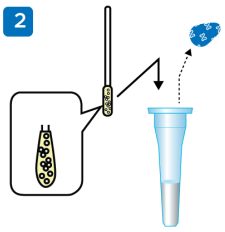
1



OPEN

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

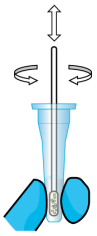
2



DIP SWAB

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

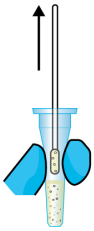
3



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

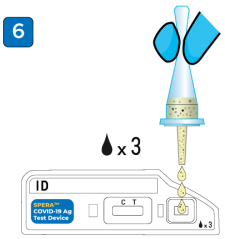
Pinch the outside of the tube above the tip at the top of the tube and pull out the swab (while squeezing the tube) to remove any remaining sample and suspension solution from the swab. The sample is stable for up to 60 minutes after preparation.

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.

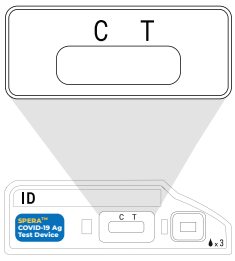
Repeat steps 1 - 6 for the second control swab.

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

IMPORTANT

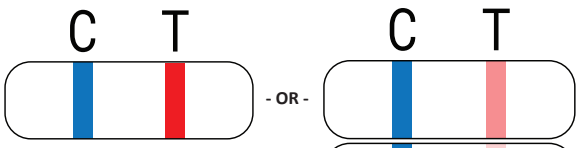
Once the sample has been applied to the sample well, allow the test device to sit undisturbed stand at 15-30°C for 15 minutes on a level surface, then interpret results. Do not read results if more than 30 minutes after applying the sample to the test device have elapsed.

Interpretation of Results



Read Test Device

POSITIVE RESULT

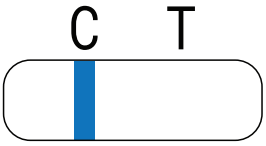


If a red "T" test line and a blue "C" control line are visible at or before 15 minutes, the test is positive and the result is valid.

Note: 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.

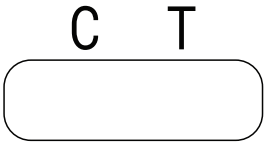
NEGATIVE RESULT



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.