SEKISUI DIAGNOSTICS

OSOM® COVID-19 Antigen Control Kit

REF 1068

For use under Emergency Use Authorization (EUA) only.
For in vitro diagnostic use.
For prescription use only.

Package contents:

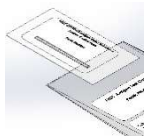
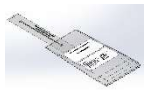
- Positive Control Swabs (QTY 5)
- Sterile Nasal Swabs (Negative Control) (QTY 5)
- Instructions For Use (QTY 1)

Materials required but not provided:

- Catalog Number 1066-40: OSOM COVID-19 Antigen Rapid Test
- Timer or watch

Summary and Explanation of the Test

SEKISUI Diagnostics provides an external positive and negative assayed quality control kit, the OSOM® COVID-19 Antigen Control Kit, to monitor the performance of the OSOM COVID-19 Antigen Rapid Test. Good laboratory practice recommends running positive and negative external controls regularly. Evaluation of external controls is recommended prior to using a new shipment or new lot of OSOM COVID-19 Antigen Rapid Test kits. Evaluation of external controls is also recommended when there is a new operator. External controls may also be used in initial laboratory validations of the OSOM COVID-19 Antigen Rapid Test in accordance with appropriate federal, state, and local guidelines or accreditation requirements, as applicable.

- Positive Control Swab: The External Positive Control Swab  consists of non-infectious recombinant SARS-CoV-2 nucleocapsid antigen spiked onto a sterile nasal swab. It is labeled specifically as the Positive Control Swab.
- Negative Control Swab: The  External Negative Control Swab consists of a sterile swab without non-infectious SARS-CoV-2 nucleocapsid recombinant antigen.

Storage Instructions

Store at 15 - 30°C.
Controls should not be used past the expiration date on the package.

Procedure / Interpretation / Limitations

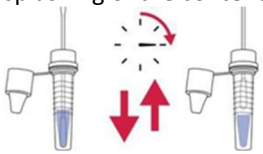
Users should refer to the OSOM COVID-19 Antigen Rapid Test Instructions for Use (Part No.: 1066-40) available on the website: sekisuidiagnostics.com

External Control Testing Procedures

1. Remove the Positive/Negative control swab from external packaging.

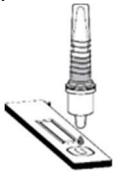
2. Remove the white cap from the collection tube and insert the first (positive or negative) control swab into the buffer.

3. Carefully plunge the control swab up and down for 15 seconds. Make sure to hold the tube in an upright position to prevent spillage or splashing of the contents.



4. Remove the control swab while pressing and rotating the tip against the inside wall of the tube to extract the liquid. Discard the swab safely. Firmly cap the collection tube with the affixed clear dropper tip.

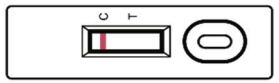
5. Remove the test device (inside 1066-40, OSOM COVID-19 Antigen Rapid Test) from the sealed foil pouch and lay flat on a clean surface.
6. Invert the capped sample extraction tube and tap the side to remove any air bubbles from the dropper tip. Hold the tube vertically, 1/4 inch above the device. Squeezing gently, dispense five (5) drops of sample solution into the sample well. Do NOT touch the sample pad with the dropper tip.



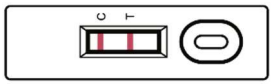
7. Wait for the colored line(s) to appear. Read results in test window 15 minutes after dispensing. Results read beyond 30 minutes may be inaccurate.
8. Repeat steps 2 – 7 for the additional control swabs.

Results Interpretation

For the negative control swab, the presence of only the control line (C) within the result window indicates the negative control has passed.



For the positive control swab, the presence of two lines, i.e., a control line (C) and a test line (T) within the result window indicates the positive control has passed.



In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of

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

Symbols

	Consult instructions for use
	Catalog number
	Contains sufficient for <n> tests per kit
	Use by
	I*n vitro* Diagnostic medical device
	Lot Number
	Temperature storage
	Single Use only
	Positive Control

If you have any questions regarding the use of this product or if you want to report any testing issues, please contact SEKISUI Diagnostics Technical Services at (800) 332-1042 or techservices@sekisuidiagnostics.com

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