

# OSOM® Flu SARS-CoV-2 Combo Control Kit

For use under Emergency Use Authorization only

## INSTRUCTIONS FOR USE



### INTENDED USE

The OSOM® Flu SARS-CoV-2 Combo Control Kit is intended for *in vitro* diagnostic use in quality control testing with the OSOM Flu SARS-CoV-2 Combo Test.

### SUMMARY

The OSOM Flu SARS-CoV-2 Combo Control kit includes five Flu A/Flu B/SARS-CoV-2 Positive Control Swabs and five Flu A/Flu B/SARS-CoV-2 Negative Control Swabs for external quality control testing. Use the OSOM Flu SARS-CoV-2 Combo Control Kit to help ensure that the OSOM Flu SARS-CoV-2 Combo Test is functioning properly and to demonstrate proper performance by the test operator. External controls are intended to monitor substantial device failure.

If External Quality Control testing fails, repeat the testing of the failed control or contact SEKISUI Diagnostics Technical Services at (800) 332-1042 or techservices@sekisuidiagnostics.com before running patient samples.

External quality control requirements should be established in accordance with local, state, and federal regulations or accreditation requirements. Minimally, SEKISUI Diagnostics recommends that positive and negative external controls be run with each new lot, shipment received, and with each new untrained operator.

### KIT CONTENTS

- 5 - Flu A / Flu B / SARS-CoV-2 Positive Control Swab (packaged with a desiccant tablet) coated with non-infectious recombinant influenza A, influenza B, and SARS-CoV-2 containing 0.05% sodium azide
- 5 - Flu A / Flu B / SARS-CoV-2 Negative Control Swab (packaged with a desiccant tablet) coated with nonviable Group C Streptococci containing 0.09% sodium azide
- 1 - OSOM Flu SARS-CoV-2 Combo Control Kit Instructions for Use

### MATERIALS REQUIRED BUT NOT PROVIDED

- OSOM Flu SARS-CoV-2 Combo Test Kit (Catalog Number 1080)
- Timer or watch

### WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
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 and influenza A/B, not for any other viruses or pathogens when used in conjunction with the OSOM Flu SARS-CoV-2 Combo Test. 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. Caution: Federal law restricts this device to sale by or on the order of a physician.
4. DO NOT use the OSOM Flu SARS-CoV-2 Combo Control Kit past the expiration date.
5. Not for patient use.
6. Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink or smoke in the area.
7. All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
8. The control swab and test device should be discarded in a proper biohazard container after testing.

## **KIT STORAGE AND STABILITY**

- The OSOM Flu SARS-CoV-2 Combo Control Kit must be stored at room temperature (15-30°C/59-86°F).
- Swabs stored in the closed tube at room temperature (15-30°C/59-86°F) are stable until the expiration date printed on the box label.

## **EXTERNAL QUALITY CONTROL TESTING PROCEDURE**

To perform a positive or negative control test, complete the steps in the Test Procedure section of the assay Instructions for Use treating the control swab in the same manner as a patient swab (refer to OSOM Flu SARS-CoV-2 Combo Test Instructions for Use).

## **EXPECTED RESULTS**

When the Flu A/Flu B/SARS-CoV-2 Positive Control Swab is tested, the appearance of ANY shade of a very light or faint pink to purple line at the "A" Test Line, "B" Test Line, and "S" Test Line, along with a "CONT" Control Line indicates that the influenza and SARS-CoV-2 antigen binding properties of the Test Stick are functional.

When the Flu A/Flu B/SARS-CoV-2 Negative Control Swab is tested, there should only be the appearance of the "CONT" Control Line without lines at the "A" Test Line, "B" Test Line, nor the "S" Test Line to indicate that there is no non-specific antigen binding and the Test Stick is functional.

Refer to the OSOM Flu SARS-CoV-2 Combo Test Instructions for Use for a complete description of the assay procedure and interpretation of results.

## **DISPOSING OF MATERIALS**

Dispose of hazardous or biologically contaminated materials according to your institution's practices. Discard all materials in a safe and acceptable manner that is in compliance with all country, state, and local requirements.

## **REORDER**

OSOM Flu SARS-CoV-2 Combo Test Kit (Catalog Number 1080)

OSOM Flu SARS-CoV-2 Combo Control Kit (Catalog Number 1079)

# SYMBOLS



Batch code



Catalog number



Consult instructions for use



*In Vitro* Diagnostic Medical Device



Quantity



Contains sufficient for <n> tests



Do not re-use



Manufacturer



Negative Control



Positive Control



Recycled content-packaging, kit box, Instructions for Use is recyclable if it can be collected, separated, or otherwise recovered from the waste stream through an established recycling program.



Caution: Federal law restricts this device to sale by or on the order of a physician.



Temperature limit



Use-by date



SEKISUI Diagnostics, LLC  
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**SEKISUI**  
**DIAGNOSTICS**

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