

**PLEASE READ THIS COVID-19 TEST KIT NOTICE CAREFULLY BEFORE PURCHASING ANY TEST KITS (DEFINED BELOW). THE TEST KITS HAVE BEEN AUTHORIZED BY THE FDA UNDER AN EMERGENCY USE AUTHORIZATION (THE "EUA"). THE EUA AND THIS NOTICE CONTAINS VERY IMPORTANT INFORMATION ABOUT CUSTOMER'S OBLIGATIONS, INCLUDING WITH RESPECT TO THE CLINICAL ADMINISTRATION OF THE TEST KITS.**

### **Information Relating to the Test Kits and Conditions of Use**

- a. The *OSOM Flu SARS-CoV-2 Combo Test* ("Test Kits"), manufactured by SEKISUI Diagnostics, LLC, are indicated for the simultaneous qualitative detection and differentiation of influenza A and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly from anterior nasal swab specimens collected of individuals with signs and symptoms of respiratory infection consistent with COVID-19 by their healthcare provider within the first four (4) days of symptom onset when tested at least twice over three days with at least 48 hours between tests. A copy of the EUA (including any existing updates) for the Test Kits is attached hereto as **Exhibit A**. **The Test Kits are not returnable and purchase orders are non-cancellable.**
- b. The Test Kits have not been FDA cleared or approved. The Test Kits have been authorized by the FDA under an EUA for use by Authorized Laboratories. "*Authorized Laboratories*" means laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, that meet the requirements to perform high, moderate, or waived complexity tests. These Test Kits are 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.
- c. Emergency use of these Test Kits is limited to Authorized Laboratories, and the Test Kits are 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner. The Test Kits have been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- d. Please be sure to read the EUA carefully, as it includes specific obligations that apply to you, including obligations to keep all records associated with the Test Kits until otherwise notified by the FDA and obligations requiring you to collect and report information on the performance of the Test Kits, including any suspected occurrence of false positive results, false negative results, and significant deviations from the established performance characteristics of the Test Kits. Please notify HSI of any complaints about the Test Kits via telephone at 1-800-472-4346.
- e. Please note that the EUA also lists material authorized to be used with the Test Kits.
- f. Please carefully read the Fact Sheet for Healthcare Providers for the Test Kits attached hereto as **Exhibit B** and provide it to your Healthcare Providers.
- g. Please carefully read the Fact Sheet for Patients attached hereto as **Exhibit C** and use it as instructed by the EUA.
- h. Please carefully read the "OSOM Flu SARS-CoV-2 Combo Test Instructions for Use" ("IFU") attached hereto as **Exhibit D** and use it as instructed by the EUA.
- i. Updated copies of the IFU, "OSOM Flu SARS-CoV-2 Combo Test Quick Reference Guide", "OSOM COVID Flu SARS-CoV-2 Combo Test Result Interpretation Card", "OSOM Flu SARS-CoV-2 Combo Control Kit instructions for Use," and the Fact Sheets are available on Henry Schein's website at [www.henryschein.com/OSOMFLU-SARs](http://www.henryschein.com/OSOMFLU-SARs).

**EXHIBIT A**

**Emergency Use Authorization**

(Starts on Following Page)



February 29, 2024

Dimitris Demirtzoglou  
Director, Regulatory Affairs  
SEKISUI Diagnostics, LLC  
6659 Top Gun Street  
San Diego, CA 92121

Device: OSOM Flu SARS-CoV-2 Combo Test

EUA Number: EUA230045

Company: SEKISUI Diagnostics, LLC

Indication: Simultaneous qualitative detection and differentiation of influenza A and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly from anterior nasal swab specimens collected of individuals with signs and symptoms of respiratory infection consistent with COVID-19 by their healthcare provider within the first four (4) days of symptom onset when tested at least twice over three days with at least 48 hours between tests. Emergency use of this test is limited to authorized laboratories.

Authorized Laboratories: 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 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.

Dear Mr. Demirtzoglou:

This letter is in response to your<sup>1</sup> request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,<sup>2</sup> pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, as amended on March 15, 2023, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that

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<sup>1</sup> For ease of reference, this letter will use the term “you” and related terms to refer to SEKISUI Diagnostics, LLC.

<sup>2</sup> For ease of reference, this letter will use the term “your product” to refer to the OSOM Flu SARS-CoV-2 Combo Test used for the indication identified above.

there is a public health emergency, or a significant potential for a public health emergency, that affects, or that has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared 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 subject to the terms of any authorization issued under Section 564(a) of the Act.<sup>3</sup>

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is included in the Instructions for Use (identified below). There are FDA-approved/cleared tests for influenza A virus and influenza B virus, but there are no FDA-approved/cleared multiplexed tests for simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A virus and/or influenza B virus antigens. Respiratory viral infections caused by the influenza A and B viruses and SARS-CoV-2 can have similar clinical presentation and diagnostic considerations. Thus, to differentially detect SARS-CoV-2, information from a test that detects and differentiates antigen from the virus that causes COVID-19 and the common influenza viruses that cause seasonal epidemics of flu, influenza A and B (not influenza C) is needed during the flu season that coincides with the COVID-19 pandemic.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

### **I. Criteria for Issuance of Authorization**

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;
2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19 through the simultaneous detection and differentiation of SARS-CoV-2, influenza A virus and/or influenza B virus protein antigens, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and

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<sup>3</sup> U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3. February 4, 2020. 85 FR 7316 (February 7, 2020). U.S. Department of Health and Human Services, *Amended Determination of a Public Health Emergency or Significant Potential for a Public Health Emergency Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3(b). March 15, 2023. 88 FR 16644 (March 20, 2023) (“Amended Determination”).

3. There is no adequate, approved, and available alternative to the emergency use of your product.<sup>4</sup>

## **II. Scope of Authorization**

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

### **Authorized Product Details**

Your product is a lateral flow immunochromatographic assay intended for in vitro rapid, simultaneous qualitative detection and differentiation of influenza A and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly from anterior nasal swab specimens of individuals with signs and symptoms of respiratory infection consistent with COVID-19 by their healthcare provider within the first four (4) days of symptom onset, when tested at least twice over three days with at least 48 hours between tests. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

Results are for the simultaneous in vitro detection and differentiation of SARS-CoV-2, influenza A virus, and influenza B virus protein antigen, but does not differentiate between SARS-CoV and SARS-CoV-2 viruses and is not intended to detect influenza C antigens. These viral antigens are 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 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. The agent detected may not be the definitive cause of the disease.

All negative results are presumptive and should be confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out influenza or 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 each respiratory infection.

Testing of anterior nasal swab specimens using your product, as outlined in the authorized labeling (described below), is limited to laboratories certified under CLIA that meet the requirements to perform moderate, high, or waived complexity tests. This product is authorized for use at the POC, i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

The anterior nasal swab specimen is tested with your product according to the "OSOM Flu SARS-CoV-2 Combo Test Instructions for Use" and the "OSOM Flu SARS-CoV-2 Combo Test Quick Reference Guide." The OSOM Flu SARS-CoV-2 Combo Test includes the materials, or other authorized materials (as may be requested under Condition P. below), necessary to collect, process and test anterior nasal swab specimens as described in the "OSOM Flu SARS-CoV-2

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<sup>4</sup> No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

Combo Test Instructions for Use” and the “OSOM Flu SARS-CoV-2 Combo Test Quick Reference Guide.”

Your product requires various types of quality control, including the procedural internal control that is built in the control line region “CONT” of the test device and the external quality controls, available from you separately as the “OSOM Flu SARS-CoV-2 Combo Control Kit” with the “OSOM Flu SARS-CoV-2 Combo Control Kit Instructions for Use,” or other authorized control materials (as may be requested under Condition P. below), to be run as outlined in the “OSOM Flu SARS-CoV-2 Combo Test Instructions for Use.”

Your product also requires the use of additional authorized materials and authorized ancillary reagents that are not included with your product and are described in the “OSOM Flu SARS-CoV-2 Combo Test Instructions for Use.”

The labeling entitled “OSOM Flu SARS-CoV-2 Combo Test Instructions for Use,” the “OSOM Flu SARS-CoV-2 Combo Test Quick Reference Guide,” the “OSOM Flu SARS-CoV-2 Combo Test Result Interpretation Card,” the “OSOM Flu SARS-CoV-2 Combo Control Kit Instructions for Use,” (available at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>), and the following fact sheets pertaining to the emergency use, is required to be made available as set forth in the Conditions of Authorization (Section III), and are collectively referred to as “authorized labeling”:

- Fact Sheet for Healthcare Providers: SEKISUI Diagnostics, LLC - OSOM Flu SARS-CoV-2 Combo Test
- Fact Sheet for Patients: SEKISUI Diagnostics, LLC - OSOM Flu SARS-CoV-2 Combo Test

The above described product, when accompanied by the authorized labeling provided as set forth in the Conditions of Authorization (Section III), is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing COVID-19, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, your product is authorized for the indication above.

### **III. Conditions of Authorization**

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

#### **SEKISUI Diagnostics, LLC (You) and Authorized Distributor(s)<sup>5</sup>**

- A. Your product must comply with the following labeling requirements pursuant to FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 CFR 809.10(b)(5), (7), and (8)); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).
- B. You and authorized distributor(s) must make your product available with the authorized labeling to authorized laboratories.
- C. You and authorized distributor(s) must make available on your website(s) the authorized labeling.
- D. You and authorized distributors must include a physical copy of the authorized “OSOM Flu SARS-CoV-2 Combo Test Instructions for Use,” the “OSOM Flu SARS-CoV-2 Combo Test Quick Reference Guide,” and the “OSOM Flu SARS-CoV-2 Combo Test Result Interpretation Card,” with each shipped product to authorized laboratories.
- E. You and authorized distributor(s) must inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and authorized labeling.
- F. Through a process of inventory control, you and authorized distributor(s) must maintain records of the authorized laboratories to which they distribute your product and number they distribute.
- G. You and authorized distributor(s) must collect information on the performance of your product. You must report any significant deviations from the established performance

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<sup>5</sup> “Authorized Distributor(s)” are identified by you, SEKISUI Diagnostics, LLC, in your EUA submission as an entity allowed to distribute your product.

characteristics of your product of which you become aware to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)-Office of In Vitro Diagnostics and Radiological Health (OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) (via email: [CDRH-EUA-Reporting@fda.hhs.gov](mailto:CDRH-EUA-Reporting@fda.hhs.gov)).

- H. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.
- I. You and authorized distributor(s) must make available the control material “OSOM Flu SARS-CoV-2 Combo Control Kit” with the “OSOM Flu SARS-CoV-2 Combo Control Kit Instructions for Use,” or other authorized control materials (as may be requested under Condition P. below), at the same time as your product.

**SEKISUI Diagnostics, LLC (You)**

- J. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).
- K. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent revisions that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).
- L. Within three months of the date of this letter, you must establish and maintain a quality system that is appropriate for your product’s design and manufacture, and that meets the requirements of either the 2016 edition of ISO 13485 or 21 CFR Part 820. You must submit to DMD/OHT7/OPEQ/CDRH a notification of compliance within this three-month timeframe.
- M. If requested by FDA, you must submit associated documents or records related to your quality system for FDA review within 48 hours of the request.
- N. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the tests released for distribution have the clinical and analytical performance claimed in the authorized labeling.
- O. If requested by FDA, you must submit lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide it within 48 hours of the request.
- P. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be



consistent with the authorized labeling and shall not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to DMD/OHT7-OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

- Q. You must evaluate the analytical limit of detection and assess traceability<sup>6</sup> of your product with any FDA-recommended reference material(s) if requested by FDA. After submission to and review and concurrence with the data by FDA, you must update labeling to reflect the additional testing if requested by FDA. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- R. You must submit your product for any FDA-recommended independent evaluation to confirm the performance characteristics of your product, if requested by FDA. After submission to, and concurrence with the data by, FDA, you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.
- S. You must further evaluate the inclusivity of your product in an FDA agreed upon post authorization inclusivity evaluation study within 3 months of the date of this letter (unless otherwise agreed to with DMD/OHT7/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you must update the authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.
- T. You must have a process in place to track adverse events and report to FDA pursuant to 21 CFR Part 803.
- U. You must evaluate the impact of SARS-CoV-2 viral mutations **and** all other target analytes on your product's performance. Such evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance concerns you or FDA identify during routine evaluation. Additionally, if requested by FDA, you must submit records of these evaluations for FDA review within 48 hours of the request. If your evaluation identifies viral mutations that affect the stated expected performance of your device, you must notify FDA immediately (via email: [CDRH-EUA-Reporting@fda.hhs.gov](mailto:CDRH-EUA-Reporting@fda.hhs.gov)).
- V. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA regarding the impact of viral mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

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<sup>6</sup> Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

### **Authorized Laboratories**

- W. Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating this labeling may be used, which may include mass media.
- X. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including authorized instruments, authorized clinical specimen types, authorized control materials, authorized ancillary reagents and authorized materials required to use your product are not permitted.
- Y. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Z. 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.
- AA. Authorized laboratories must collect information on the performance of your product and must report any significant deviations from the established performance characteristics of your product of which they become aware to DMD/OHT7-OIR/OPEQ/CDRH (via email: [CDRH-EUA-Reporting@fda.hhs.gov](mailto:CDRH-EUA-Reporting@fda.hhs.gov)) and you (via email at [techservices@sekisuidiagnostics.com](mailto:techservices@sekisuidiagnostics.com) or via phone at (800) 332-1042).
- BB. 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.

### **SEKISUI Diagnostics, LLC (You), Authorized Distributor(s) and Authorized Laboratories**

- CC. You, authorized distributors, and authorized laboratories using your product must 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.

### **Conditions Related to Printed Materials, Advertising and Promotion**

- DD. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act, as applicable, and FDA implementing regulations.
- EE. No descriptive printed matter, advertising, or promotional materials relating to the use of your product may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2, influenza A and influenza B.
- FF. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories;
- This product has been authorized only for the detection of proteins from SARS-CoV-2, influenza A and influenza B, not for any other viruses or pathogens; and,
- 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.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

#### **IV. Duration of Authorization**

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

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Jeffrey E. Shuren, M.D., J.D.  
Director  
Center for Devices and Radiological Health  
Food and Drug Administration

Enclosure

# **EXHIBIT B**

## **Fact Sheet for Healthcare Providers**

(Starts on Following Page)

**OSOM® FLU SARS-COV-2 COMBO TEST****SEKISUI Diagnostics, LLC**

February 29, 2023

**All individuals whose specimens are tested with this product will receive the Fact Sheet for Patients for the product.**

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This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the OSOM® Flu SARS-CoV-2 Combo Test.

**WHERE CAN I GO FOR GENERAL INFORMATION ON COVID-19 AND INFLUENZA?**

For general information on COVID-19 and influenza, including the symptoms of COVID-19 and influenza, infection control precautions, and other information please check the CDC COVID-19 and influenza webpages (see links provided in “*Where can I go for updates and more information?*” section at the end of this document) or your local jurisdiction’s website for the most up to date information.

**WHAT DO I NEED TO KNOW ABOUT COVID-19 AND INFLUENZA TESTING WITH THIS PRODUCT?**

- The OSOM® Flu SARS-CoV-2 Combo Test can be used to test anterior nasal swab specimens.
- The OSOM® Flu SARS-CoV-2 Combo Test should be ordered for the detection and differentiation of SARS-CoV-2, influenza A and influenza B antigens by a healthcare provider.
- The OSOM® Flu SARS-CoV-2 Combo Test is authorized for use in individuals with signs and symptoms of respiratory infection consistent with COVID-19 by their healthcare provider within the first four (4) days of symptom onset when tested at least twice over three days with at least 48 hours between tests.
- Consistent with serial testing recommendations for SARS-CoV-2, for multi-analyte tests such as the OSOM® Flu SARS-CoV-2 Combo Test, symptomatic individuals who test positive for influenza A or B on the initial test but test negative for SARS-CoV-2 should be tested again in 48 hours to evaluate for co-infection with SARS-CoV-2. Please refer to the healthcare provider instructions for use for more information on serial testing.
- The OSOM® Flu SARS-CoV-2 Combo Test is authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests.
- The OSOM® Flu SARS-CoV-2 Combo 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.
- Please refer to the OSOM® Flu SARS-CoV-2 Combo Test Instructions for Use for additional information.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the lower 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 or influenza as compared to a molecular test, especially in samples with low viral load.

Specimens should be collected with appropriate infection control precautions. When collecting and handling specimens from individuals suspected of being infected with the virus that causes

COVID-19, appropriate personal protective equipment should be used as outlined in the CDC *Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)*. For additional information, refer to CDC *Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing*.

### **WHAT DOES IT MEAN IF THE SPECIMEN TESTS POSITIVE FOR SARS-COV-2, INFLUENZA A, OR INFLUENZA B VIRUSES?**

A positive test result for COVID-19 or influenza indicates that antigens from either SARS-CoV-2, influenza A or influenza B were detected, and therefore the individual being tested is infected with the virus and presumed to be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiological data (such as local prevalence rates and current outbreak/epicenter locations) in determining individual diagnosis and patient management decisions and should follow current CDC guidelines.

The OSOM® Flu SARS-CoV-2 Combo Test has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks could include the following: a needless recommendation for the patient to isolate that might limit contact with family or friends and the ability to work, delayed diagnosis and treatment for the true infection causing the patient's symptoms, potentially increased likelihood that the patient could contract COVID-19 or influenza from other potentially COVID-19 or influenza positive patients isolated in the same areas, unnecessary prescription of a treatment or therapy, needless monitoring of close contacts for symptoms, or other unintended adverse effects. False positive results for any virus are more likely when prevalence of that virus in the community are low.

All laboratories using this test must follow the standard testing and reporting guidelines according to their appropriate public health authorities.

### **WHAT DOES IT MEAN IF THE SPECIMEN TESTS NEGATIVE FOR THE SARS-COV-2, INFLUENZA A, AND INFLUENZA B VIRUSES?**

COVID-19 negative samples should be repeated as per the FDA Serial Testing Guidance (see link provided in "*Where can I go for updates and more information?*" section at the end of this document). A negative serial test result for this test means that SARS-CoV-2, influenza A and influenza B antigens were not present in the specimen above the limit of detection. All SARS-CoV-2 negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. All negative influenza A and B test results are presumptive. It is recommended these results be confirmed by an FDA-cleared influenza A and B molecular assay. However, a negative result does not rule out COVID-19 or influenza and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions (such as discontinuation of isolation precautions). Antigen tests are known to be less sensitive than molecular tests that detect viral nucleic acids.

It is possible to test a person too early or too late during SARS-CoV-2, influenza A or influenza B infection to make an accurate diagnosis via the OSOM® Flu SARS-CoV-2 Combo Test.

The amount of antigen in a sample may decrease as the duration of illness increases. For COVID-19 testing, specimens collected after day four (4) of illness may be more likely to be negative compared to a RT-PCR assay. Therefore, negative SARS-CoV-2 results from patients

with symptom onset beyond four (4) days should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of an individual's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19 or influenza. The possibility of a false negative result should especially be considered if the individual's recent exposures or clinical presentation indicate that COVID-19 or influenza is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If COVID-19 or influenza is still suspected based on exposure history together with other clinical findings, re-testing or testing with molecular methods should be considered by healthcare providers in consultation with public health authorities. Additional testing may be helpful to ensure testing was not conducted too early.

Risks to a patient of a false negative test result include delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of COVID-19 or influenza spread within the community, or other unintended adverse events.

For additional recommendations regarding infection control, refer to CDC's *Ending Isolation and Precautions for People with COVID-19: Interim Guidance* and CDC's general isolations precautions webpage (see links provided in "Where can I go for updates and more information?" section).

The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between October 2023 and January 2024. The clinical performance has not been established in 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 SARS-CoV-2 or influenza and their prevalence, which change over time.

### **WHAT DOES IT MEAN IF THE SPECIMEN TESTS POSITIVE FOR SARS-COV-2 AND ONE OR BOTH INFLUENZA (A AND/OR B) VIRUSES? IS CO-INFECTION POSSIBLE?**

Yes, it is possible for an individual to be infected with influenza A virus, influenza B virus, and/or SARS-CoV-2 simultaneously. A positive test result for the viruses that cause COVID-19 and influenza A and/or B indicates that antigens from these viruses were detected, the patient may be co-infected, and is presumed to be contagious. Laboratory test results should always be considered in the context of clinical findings and observations and epidemiological data in making a final diagnosis. Patient management decisions should be made with a healthcare provider and follow current CDC guidelines.

### **WHAT DO I NEED TO KNOW ABOUT SERIAL TESTING?**

Serial testing of individuals whose initial COVID-19 test result is negative assists in identifying infected individuals earlier and facilitate timely infection control practices. A negative test result for COVID-19 does not rule out infection in symptomatic individuals; repeating testing twice over three days with at least 48 hours between tests may decrease the risks of false negative results. If COVID-19 infection is still suspected based on symptoms, exposures, or other factors, additional testing with a laboratory-based molecular test should be considered.

For additional recommendations regarding confirmation of antigen test results, please refer to the CDC's *Guidance for Antigen Testing for SARS-CoV-2 for Healthcare Providers Testing Individuals in the Community* (see links provided in "Where can I go for updates and more information" section).

## **WHAT IS AN EUA?**

The U.S. FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19.

An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in diagnosing COVID-19.

The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless the declaration is terminated or authorization is revoked sooner.

## **WHAT ARE THE APPROVED AVAILABLE ALTERNATIVES?**

Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here:

<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases>. A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. FDA has issued EUAs for other tests that can be found at:

<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

## **WHERE DO I REPORT ADVERSE EVENTS?**

**Report Adverse events**, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500

(<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) or by calling **1-800-FDA-1088**

## **WHERE CAN I GO FOR UPDATES AND MORE INFORMATION?**

### **CDC COVID-19 WEBPAGES:**

General: <https://www.cdc.gov/coronavirus/2019-ncov/index.html>

Symptoms: <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>

Healthcare Professionals: <https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html>

Information for Laboratories: <https://www.cdc.gov/coronavirus/2019-nCoV/lab/index.html>

Laboratory Biosafety: <https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html>



Isolation Precautions in Healthcare Settings: <https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html>

Specimen Collection: <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>

Infection Control: <https://www.cdc.gov/coronavirus/2019-ncov/php/infection-control.html>

Discontinuation of Isolation: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html>

Antigen Testing: <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html>

## **CDC WEBPAGES**

Flu General: <https://www.cdc.gov/flu/index.htm>

Infection Control – Isolation Precautions: <https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html>

## **FDA WEBPAGES:**

General: [www.fda.gov/novelcoronavirus](http://www.fda.gov/novelcoronavirus)

EUAs: (includes links to patient fact sheet and manufacturer’s instructions) <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>

Serial Testing: <https://www.fda.gov/medical-devices/safety-communications/home-covid-19-antigen-tests-take-steps-reduce-your-risk-false-negative-results-fda-safety>

## **SEKISUI DIAGNOSTICS, LLC:**

6659 Top Gun Street

San Diego, CA 92121 USA

### **Technical Support:**

SEKISUI Diagnostics Technical Services: (800) 332-1042 or [techservices@sekisuidiagnostics.com](mailto:techservices@sekisuidiagnostics.com)

**EXHIBIT C**

**Fact Sheet for Patients**

**(Starts on Following Page)**

**OSOM® FLU SARS-COV-2 COMBO TEST****SEKISUI Diagnostics, LLC**

February 29, 2023

For the most up to date COVID-19 information, including symptoms, please visit [Coronavirus Disease 2019 \(COVID-19\) | CDC](#)

For the most up to date Influenza information, including symptoms, please visit [Influenza \(Flu\) | CDC](#)

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Your sample(s) was tested for COVID-19 and influenza using the OSOM® Flu SARS-CoV-2 Combo Test.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of COVID-19 and influenza. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

**WHAT IS COVID-19 (CORONAVIRUS DISEASE 2019)?**

COVID-19 is a disease caused by the SARS-CoV-2 virus.

**WHAT IS INFLUENZA?**

Influenza (flu) is a disease caused by influenza viruses. There are two main types of influenza viruses: types A and B. Both type A and B influenza viruses regularly spread in people and are responsible for seasonal flu each year.

**WHAT IS THE OSOM® FLU SARS-COV-2 COMBO TEST?**

The OSOM® Flu SARS-CoV-2 Combo Test is a type of test called an antigen test. This antigen test is designed to detect proteins from three types of viruses: two viruses that cause influenza (type A and type B) and the virus that causes COVID-19 in nasopharyngeal and anterior nasal swab specimens.

**WHY WAS MY SPECIMEN TESTED?**

Testing of your specimen(s) will help find out if you may have COVID-19 and/or influenza.

**WHAT ARE THE KNOWN AND POTENTIAL RISK AND BENEFITS OF THE TEST?**

Potential risks include:

- Possible discomfort or other complications that can happen during specimen collection.
- Possible incorrect test result (see below for more information).

Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 and/or influenza to your family and those you come in contact with.

**WHAT DOES A POSITIVE TEST RESULT FOR THE SARS-COV-2 VIRUS MEAN?**

If you have a positive test result for COVID-19 with the OSOM® Flu SARS-CoV-2 Combo Test, it is very likely that you have COVID-19 because proteins from the virus that causes COVID-19

were found in your sample. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. You should follow CDC guidance to reduce the potential transmission of disease.

There is a chance that this test can give a positive result that is wrong (a false positive result) particularly when used in a population without many cases of COVID-19. Your healthcare provider will work with you to determine how best to care for you based on the test results along with medical history, and your symptoms. Your healthcare provider may recommend a confirmatory test, depending on your clinical history and risk factors.

### **WHAT DOES A POSITIVE TEST RESULT FOR INFLUENZA A AND/OR B VIRUSES MEAN?**

If you have a positive test result for the presence of influenza A and/or influenza B viruses, it is very likely that you have the flu. If you have a positive result for an influenza virus, your healthcare provider will determine the best way to care for you based on the test results along with other factors in your medical history. There is a very small chance that this test can give a positive result that is wrong (a false positive result). Your healthcare provider will work with you to determine how best to care for you based on the test results, medical history, and your symptoms.

### **WHAT DOES IT MEAN IF I HAVE A POSITIVE TEST RESULT FOR SARS-COV-2 AND INFLUENZA (A AND/OR B) VIRUSES?**

It is possible for an individual to be infected with influenza A virus, influenza B virus, and/or SARS-CoV-2 virus at the same time. Your healthcare provider will work with you to determine how best to care for you based on these test results, your medical history, and your symptoms.

### **WHAT DOES IT MEAN IF I HAVE AN INITIAL NEGATIVE TEST RESULT FOR SARS-COV-2?**

If your initial test result was negative for SARS-CoV-2 you should have serial testing performed (see below) and if after serial testing your test result is negative this means that antigens of the virus that causes COVID-19 were not found in your sample.

### **WHAT DOES IT MEAN IF I HAVE A NEGATIVE SERIAL TEST RESULT FOR SARS-COV-2, INFLUENZA (A AND/OR B) VIRUSES?**

If your test result was negative after serial testing (the second test) for SARS-CoV-2, influenza A and influenza B viruses then antigens to those viruses were not found in your sample. Due to the sensitivity of antigen tests compared to molecular COVID-19 or influenza tests, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19 or influenza. For example, if you are tested too early during your infection. This means that you could possibly still have COVID-19 or influenza even though the test result is negative. If your test is negative, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you. The amount of antigen in a sample may decrease the longer you have symptoms of infection. For COVID-19 testing, specimens collected after you have had symptoms for more than four (4) days may be more likely to be negative compared to a molecular assay. It is important that you work with your healthcare provider to help you understand the next steps you should take.

## WHAT IS SERIAL TESTING?

Serial testing is when a single person is tested for COVID-19 more than once using the same test. Because the amount of antigen in your sample may change over time and COVID-19 antigen tests have lower sensitivity than COVID-19 molecular tests, false results may occur. Therefore, repeated testing can identify more individuals with COVID-19 than testing a single time. By repeating testing, it may be possible to more quickly identify cases of COVID-19 and reduce spread of infection. Additional testing with a molecular COVID-19 test may be necessary, depending on your individual risk factors and test results. Because it is possible to have infection with the COVID-19 and influenza, individuals who test positive for influenza but negative for COVID-19 on the initial test should still be tested again 48 hours after the first test.

## WHAT ARE THE DIFFERENCES BETWEEN ANTIGEN TESTS AND OTHER COVID-19 TESTS?

There are different kinds of tests for diagnosing COVID-19. Molecular tests (also known as PCR tests) detect genetic material from the virus. Antigen tests detect proteins from the virus. Antigen tests are very specific for the virus, but are not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection. If your test result is negative, you should discuss with your healthcare provider whether an additional molecular test would help with your care, and when you should discontinue home isolation. If you do not have an additional test to determine if you are infected and may spread the infection to others, the CDC currently recommends that you should stay home until three things have happened:

- You have had no fever for at least 24 hours (that is one full day of no fever without the use of medicine that reduces fevers); **AND**
- Other symptoms have improved (for example, when your cough or shortness of breath has improved) **\*\*Loss of taste and smell may persist for weeks or months after recovery and need not delay the end of isolation; AND**
- At least 5 days have passed since your symptoms first appeared.

For more information, the CDC has provided guidelines on how to prevent the spread of COVID-19 if you are sick: <https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/index.html>

## WHAT IS AN EUA?

This test has been issued an Emergency Use Authorization (EUA) by the U.S. FDA. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. The EUA for this test is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics for the detection and/or diagnosis of the virus that causes COVID-19. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying the emergency use of in vitro diagnostics, unless the declaration is terminated or authorization is revoked sooner.). An EUA is NOT an FDA-approval or clearance.

## WHAT ARE THE APPROVED AVAILABLE ALTERNATIVES?

Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here:

<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases>.

A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. FDA has issued EUAs for other tests that can be found at:

<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

# **EXHIBIT D**

## **Instructions for Use**

**(Starts on Following Page)**

# OSOM<sup>®</sup>

## Flu SARS-CoV-2 Combo Test

**For use under Emergency Use  
Authorization (EUA) only**

**For *in vitro* diagnostic use**

**For use with anterior nasal swab specimens.**

**INSTRUCTIONS FOR USE**

 **IVD**  **Rx ONLY**  **REF** **1080**

### **INTENDED USE**

The OSOM<sup>®</sup> Flu SARS-CoV-2 Combo Test is a lateral flow immunochromatographic assay intended for *in vitro* rapid, simultaneous qualitative detection and differentiation of influenza A and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly from anterior nasal swab specimens of individuals with signs and symptoms of respiratory infection consistent with COVID-19 by their healthcare provider within the first four (4) days of symptom onset when tested at least twice over three days with at least 48 hours between tests. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar. 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.

Results are for the simultaneous *in vitro* detection and differentiation of SARS-CoV-2, influenza A virus, and influenza B virus protein antigen, but does not differentiate, between SARS-CoV and SARS-CoV-2 viruses and is not intended to detect influenza C antigens.

These viral antigens are 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 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. The agent detected may not be the definitive cause of disease.

All negative results are presumptive, and should be confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out influenza or 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 each respiratory infection.

The OSOM Flu SARS CoV-2 Combo 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**

Along with the common cold, influenza is one of the most common acute respiratory infections, producing symptoms such as headache, chills, dry cough, body aches, and fever. It affects 5%-20% of the United States population annually, resulting in more than 200,000 hospitalizations and 36,000 deaths.<sup>1</sup> The influenza A virus is typically more prevalent and is associated with the most serious influenza epidemics, while influenza B infections usually present with milder symptoms. Diagnosis is difficult because the initial symptoms can be similar to those caused by other infectious agents. Considering that the influenza virus is highly contagious, accurate diagnosis and prompt treatment of patients can have a positive effect on public health. Accurate diagnosis and the ability to distinguish between A or B antigens can also help reduce the inappropriate use of antibiotics and gives the physician the opportunity to prescribe an antiviral therapy. Initiation of antiviral therapy should begin as soon as possible after onset, ideally within 48 hours of the appearance of symptoms, as treatment may reduce the duration of symptoms.<sup>2</sup>

Coronaviruses are enveloped RNA viruses that are found broadly among humans, other mammals, and birds. The viruses are known to cause mild symptoms, but sometimes severe respiratory, enteric, hepatic, and neurological diseases can occur. Seven coronavirus species are known to cause human disease, four of which (229E, OC43, NL63 and HKU-1) are quite prevalent and can cause mild cold symptoms, especially in immunocompetent people.<sup>3</sup> There are three other strains that are known to cause severe acute respiratory disease. These strains include severe acute respiratory syndrome coronavirus (SARS-CoV), Middle East respiratory syndrome coronavirus (MERS-CoV), and the 2019 Novel Coronavirus (COVID-19). These strains are all zoonotic in origin and have been linked to sometimes fatal respiratory illness. The prevalence of SARS and MERS has been quite low in recent years; the Novel Coronavirus (COVID-19) was recently identified in December 2019. The main manifestations of illness include fever, fatigue, and dry cough. Nasal congestion, runny nose, sore throat, myalgia, and diarrhea are found in a few cases. Most epidemiological studies suggest a 1-14 day incubation period. The median incubation period is estimated at 5.1 days, with most developing symptoms before 11.5 days.<sup>4</sup> Infected but asymptomatic people can also be an infectious source. The OSOM Flu SARS-CoV-2 Combo Test can provide rapid detection of influenza A, influenza B, and/or SARS-CoV-2 viral antigens from symptomatic patients.

## **PRINCIPLE OF THE PROCEDURE**

The OSOM Flu SARS-CoV-2 Combo Test consists of a Test Stick that separately detects influenza A, influenza B, and SARS-CoV-2 antigens. The test procedure requires the solubilization of the nucleoproteins from a nasal swab sample by mixing the swab in an Extraction Buffer vial. The Test Stick is then placed in the sample mixture, which migrates along the membrane surface. If influenza A, influenza B, and/or SARS-CoV-2 viral antigens are present in the sample, it will form a complex with mouse monoclonal IgG antibodies to influenza A, influenza B and/or SARS-CoV-2 conjugated to colloidal gold. The complex will then be bound by another rat anti-influenza A, mouse anti-influenza B and/or mouse anti SARS-CoV-2 antibody coated on the nitrocellulose membrane. A pink to purple control line must appear in the control region of the Test Stick for results to be valid. The appearance of a second and possibly third or fourth light pink to purple line in the test line region indicates a influenza A, influenza B, and/or SARS-CoV-2 positive result. A visible control line with no test line is a negative result.

## KIT CONTENTS

- 25 - Sterile Nasal Swabs
- 27\* - Test Sticks
- 27\* - Extraction Buffer vials each containing 0.25 mL phosphate buffered salt solution (with 0.09% sodium azide as a preservative)
- 1 - 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
- 1 - 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
- 2 - Result Interpretation Cards
- 1 - Instructions for Use (IFU)
- 1 - Quick Reference Guide (QRG)
- 1 - Workstation

**\*NOTE:** Two extra Test Sticks and Extraction Buffer vials have been included in the kit for External Quality Control (QC) testing.

## MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or clock
- OSOM Flu SARS-CoV-2 Combo Control Kit for additional quality control (Catalog Number 1079)

## WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- 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, influenza A and influenza B, 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.
- The test has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories certified under the CLIA 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.
- **Serial testing should be performed in individuals with SARS-CoV-2 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.**
- **Consistent with serial testing recommendations for SARS-CoV-2, for multi-analyte tests, symptomatic individuals who test positive for influenza A or B on the initial test but test negative for SARS-CoV-2 should be tested again in 48 hours to evaluate for co-infection with SARS-CoV-2 infection.**
- Do not use the kit contents beyond the expiration date printed on the outside of the box.
- Swabs, Extraction Buffer Vials, and Test Sticks are for single use only (do not reuse).
- If any liquid spills from the buffer tube, discard test components and re-start test using new test components.
- The Extraction Buffer vial contains only enough liquid for one test. Do not add a second Test Stick to the same Extraction Buffer vial as invalid or incorrect results may occur.
- Do not interchange or mix components from different kit lots.

- Follow your clinical and/or laboratory safety guidelines and use appropriate precautions in the collection, handling, storage, and disposal of patient samples, all used kit contents, and all items exposed to patient samples.<sup>5</sup>
- Use of nitrile or latex (or other equivalent) gloves and other personal protective equipment are recommended when handling patient samples.<sup>5</sup>
- Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
- Only use the nasal swabs provided in the kit. Do not touch the swab tip prior to testing.
- Once removed from the canister, the Test Stick should be used within 30 minutes.
- **Do not read test results before 10 minutes or after 30 minutes. Results read before 10 minutes or after 30 minutes may lead to a false positive, false negative, or invalid results.**
- Dispose of unused contents and containers in accordance with federal, state, and local regulations.
- The Result Interpretation Card should be cleaned after each use by spraying the laminated card with 70% ethanol alcohol or alternately by wiping with a clean towel moistened with 70% ethanol alcohol. The Result Interpretation Card should be wiped dry with a clean towel.
- Eyewear protection is recommended.
- **Keep testing kit and kit components away from children and pets before and after use. 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

| Chemical Name CAS                   | GHS Code for each Ingredient                                                                                 | Concentration (%) |
|-------------------------------------|--------------------------------------------------------------------------------------------------------------|-------------------|
| Sodium Azide 26628-22-8             | Acute Tox. 2 (Oral), H300<br>Acute Tox. 1 (Dermal), H310<br>Aquatic Acute 1, H400<br>Aquatic Chronic 1, H410 | 0.09%             |
| Dodecan-1-ol, ethoxylated 9002-92-0 | Acute Tox. 4 (Oral), H302<br>Skin Irrit. 2, H315<br>Eye Dam. 1, H318<br>Aquatic Acute 2, H401                | 0.6%              |

- 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](http://www.cdc.gov/COVID19)

## KIT STORAGE AND STABILITY

Store the OSOM Flu SARS-CoV-2 Combo Test at room temperature (15-30°C/59-86°F) in the original packaging, away from direct sunlight. Kit contents are stable in the unopened canister until the expiration date printed on the kit box.

- Do not freeze any of the test kit components.
- Do not use Test Sticks or Extraction Buffer after expiration date.
- Recap the desiccated Test Stick canister immediately after removing a Test Stick.
- Test Sticks that have been outside of the desiccated container for more than 30 minutes should be discarded.

## **SAMPLE HANDLING, TRANSPORT AND STORAGE**

- The test performance depends on the quality of the sample obtained as well as the handling and transport of the sample. Negative results can occur from inadequate sample collection and/or handling. Training in specimen collection is highly recommended because of the importance of specimen quality.
- To obtain accurate results, do not use visually bloody or overly viscous samples.
- If a culture result is desired for influenza, a separate swab must be collected for the culture.
- Freshly collected patient samples should be processed in the Extraction Buffer vial as soon as possible after collection. If the sample cannot be processed immediately, the patient swab may be stored at room temperature (15-30°C/59-86°F) for up to 30 minutes or refrigerated (2-8°C/36-46°F) for up to 30 minutes prior to testing in a clean dry container. Refrigerated samples should come to room temperature before testing.
- To transport patient samples, place swab in a clean, dry container such as a plastic or glass tube.
- Once the swab has been mixed in the Extraction Buffer vial, the extracted sample must be used within 30 minutes when stored at room temperature (15-30°C/59-86°F) or refrigerated (2-8°C/36-46°F).

## **QUALITY CONTROL**

The OSOM Flu SARS-CoV-2 Combo Test provides two types of controls: internal procedural controls to aid in determining test validity, and two external controls, a positive and negative control swab.

### ***Internal Procedural Controls***

Several controls are incorporated into each Test Stick as routine quality checks for the test system and operator.

1. The appearance of the control line in the results window is an internal procedural control. It also verifies proper assembly of the Test Stick. If the control line does not appear at the read time, the test is invalid.
2. The clearing of the background in the results area is another internal procedural control. It also serves as an additional capillary flow control. At the read time, the background should appear white to light pink and not interfere with the reading of the test. If the background color does not clear and interferes with the test result, the test is invalid.

**Contact SEKISUI Diagnostics Technical Services at (800) 332-1042 or [techservices@sekisuidiagnostics.com](mailto:techservices@sekisuidiagnostics.com) if you experience a problem.**

### ***External Quality Control Testing***

The OSOM Flu SARS-CoV-2 Combo Test kit includes one combined positive control swab that contains recombinant antigen for influenza A, influenza B, and SARS-CoV-2 and one negative control swab that contains non-viable Group C Streptococci.

Use the controls to help ensure that the Test Sticks are functioning properly and to demonstrate proper performance by the test operator. It is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure was run correctly and to verify the test is working properly.

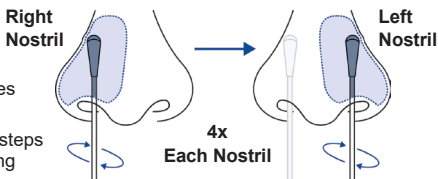
External quality control requirements should be established in accordance with your local, state, and federal regulations or accreditation requirements. To perform a positive or negative control test, complete the steps in the Test Procedure section, treating the control swab in the same manner as a patient swab. Minimally, SEKISUI Diagnostics recommends that Positive and Negative external controls be run with each new lot, shipment received, and with each new untrained operator

## SPECIMEN COLLECTION AND PREPARATION

Only nasal swabs can be used with this test. Use of nasal washes, nasal aspirates or nasopharyngeal swabs has not been validated.

### Nasal Swab Sample

1. Gently insert the sterile swab no more than 3/4 of an inch into the nostril.
2. Rotate the swab at least 4 times against the nasal wall.
3. Remove the swab and repeat steps 1 and 2 in the other nostril using the same swab.
4. Sample should be processed in the Extraction Buffer as soon as possible after collection. Sample must be mixed in the extraction buffer within 30 minutes of sample collection.

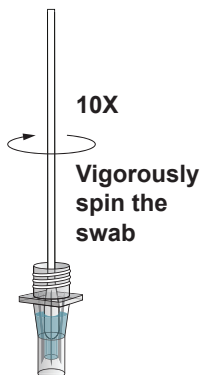


## TEST PROCEDURE

- 1** **Twist** cap off Buffer vial. **Insert** the swab through the ridges into the liquid.

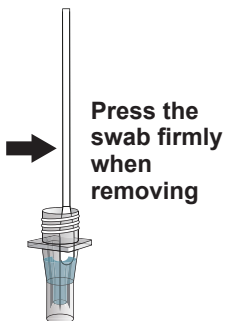
**Mix** thoroughly by spinning the swab **at least 10 times** in the liquid.

**NOTE:** Nasal swabs may not reach the bottom of the vial. Ensure that the swab is fully immersed in the liquid when mixing.



- 2** **Press** the swab against the side of the vial to remove any excess sample in the swab.

**Remove** and **Discard** the swab.



- 3 **Insert** Test Stick (arrows pointing downward) into the vial.

**Set** a timer for **10 minutes**

**NOTE:** Leave the Test Stick in the vial for the full 10 minutes.

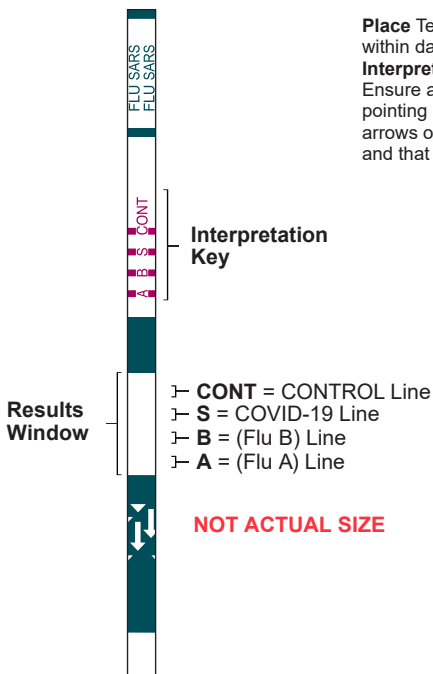
- !** **DO NOT** handle or remove for at least **10 minutes**.

- 4 **Read** test at 10 minutes. Do not read test before 10 minutes or after 30 minutes.  
See **Interpretation of Results**.



**NOTE:** You may need to remove the Test Stick to read the test results.

## INTERPRETATION OF RESULTS

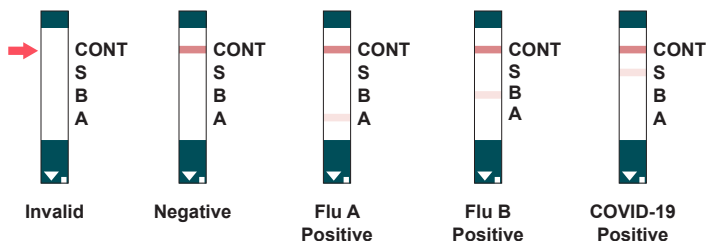


**Place** Test Stick, arrows pointing down, within dashed area of the **Result Interpretation Card** included in the kit. Ensure arrows on the Test Stick are pointing in the same direction as the arrows on the **Result Interpretation Card** and that the **Results Window** is aligned.

- └ CONT = CONTROL Line
- └ S = COVID-19 Line
- └ B = (Flu B) Line
- └ A = (Flu A) Line

**NOT ACTUAL SIZE**

## INTERPRETATION OF RESULTS



### +LOOK CLOSELY WHEN INTERPRETING THE RESULTS!

The Control Line must be present for the result to be valid.

The appearance of **ANY** shade of a very light or faint pink to purple line at the Influenza “A” Test Line, Influenza “B” Test Line, or SARS-CoV-2 “S” Test Line along with a “CONT” Control Line indicates a positive result for the respective target according to the examples above.

**Even if you see a very light or faint pink to purple Test Line, as long as the Control Line is present, it is a positive test result.**



It is possible to have **more than one positive Test Line**, which could indicate a co-infection with influenza A, B, and/or SARS-CoV-2.

If more than one positive Test Line is observed, retest with a new patient sample, Extraction Buffer vial, and Test Stick. A differing result should be followed by confirmatory testing with another test method, such as PCR.

### INVALID RESULT

If the pink to purple Control Line does not appear, even if **ANY** shade of a very light or faint pink to purple line appears at any of the Test Lines, the result is considered invalid. If at 10 minutes the background does not clear, and it interferes with the reading of the test, the result is considered invalid. If the test is invalid, a new test should be performed with a new patient sample, Extraction Buffer vial, and Test Stick.

### NEGATIVE RESULT

At 10 minutes, the appearance of **ONLY** the pink to purple Control Line indicates that influenza A, influenza B, or SARS-CoV-2 has **NOT** been detected. A negative result should be reported as a presumptive negative for the presence of influenza and/or SARS-CoV-2 antigen.

**NOTE:**

#### COVID-19 Negative (-) Result

**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.

## **POSITIVE RESULT**

The appearance of **ANY** shade of a very light or faint pink to purple line at the Influenza “A” Test Line, Influenza “B” Test Line, and/or SARS-CoV-2 “S” Test Line along with a “CONT” Control Line indicates a positive result for the presence of influenza A, influenza B, and/or SARS-CoV-2 viral antigen. A positive result does not rule out co-infections with other pathogens or identify any specific influenza A subtype, influenza B lineage, or SARS-CoV-2 variant.

**NOTE:** Positive test lines are usually very prominent but at times may vary in shade and intensity. A pink to purple line of any intensity or thickness in the A, B, or S region is considered a positive result. The intensity of the Control Line should not be compared to that of the Test Line for the interpretation of the test result.

Take time to look at test lines very carefully. If you see a very light or faint pink to purple Test Line, this is considered a POSITIVE result.

**NOTE:** It is possible to have more than one positive Test Line, which could indicate a co-infection with influenza A, B, and/or SARS-CoV-2. If more than one positive Test Line is observed, retest with a new patient sample, Extraction Buffer vial, and Test Stick. Repeatable influenza A and B “dual positive” results should be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay before reporting results.

### **COVID-19 Positive (+) Result**

**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 (a false positive).

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 OSOM Flu SARS-CoV-2 Combo 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.

Repeat Testing is needed to improve test accuracy for negative SARS-CoV-2 results. Please follow the table below when interpreting test results with symptoms. Serial (repeat) SARS-CoV-2 testing does not need to be performed if patients have a positive SARS-CoV-2 result.



| Status on First Day of Testing | Day 0 (First Test)                         | Serial Testing? | Day 2 (Second Test)                        | Final Interpretation                                                    |
|--------------------------------|--------------------------------------------|-----------------|--------------------------------------------|-------------------------------------------------------------------------|
| With Symptoms                  | SARS-CoV-2 (+)<br>Influenza A and B (-)    | NO              | Not needed                                 | Positive for COVID-19<br>Presumptive negative for Influenza             |
|                                | SARS-CoV-2 (+)<br>Influenza A and/or B (+) | NO              | Not needed                                 | Positive for COVID-19<br>Positive for Influenza A and/or B              |
|                                | SARS-CoV-2 (-)<br>Influenza A and/or B (-) | YES             | SARS-CoV-2 (+)<br>Influenza A and/or B (-) | Positive for COVID-19<br>Presumptive Negative for Influenza             |
|                                | SARS-CoV-2 (-)<br>Influenza A and/or B (+) | YES             | SARS-CoV-2 (+)<br>Influenza A and/or B (+) | Positive for COVID-19<br>Positive for Influenza A and/or B              |
|                                | SARS-CoV-2 (-)<br>Influenza A and/or B (-) | YES             | SARS-CoV-2 (-)<br>Influenza A and/or B (+) | Presumptive Negative for COVID-19<br>Positive for Influenza A and/or B  |
|                                | SARS-CoV-2 (-)<br>Influenza A and/or B (-) | YES             | SARS-CoV-2 (-)<br>Influenza A and/or B (-) | Presumptive Negative for COVID-19<br>Presumptive Negative for Influenza |
|                                | SARS-CoV-2 (-)<br>Influenza A and/or B (-) | YES             | SARS-CoV-2 (+)<br>Influenza A and/or B (+) | Positive for COVID-19<br>Positive for Influenza A and/or B              |
|                                | SARS-CoV-2 (-)<br>Influenza A and/or B (+) | YES             | SARS-CoV-2 (-)<br>Influenza A and/or B (-) | Presumptive Negative for COVID-19<br>Positive for Influenza A and/or B  |
|                                | SARS-CoV-2 (-)<br>Influenza A and/or B (+) | YES             | SARS-CoV-2 (-)<br>Influenza A and/or B (+) | Presumptive Negative for COVID-19<br>Positive for Influenza A and/or B  |
|                                | SARS-CoV-2 (-)<br>Influenza A and/or B (+) | YES             | SARS-CoV-2 (+)<br>Influenza A and/or B (+) | Positive for COVID-19<br>Positive for Influenza A and/or B              |

## LIMITATIONS

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between October 2023 and January 2024. 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 SARS-CoV-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 SARS- CoV-2 as compared to a molecular test, especially in samples with low viral load.

- All antigen test negative results, for SARS- CoV-2 or influenza, 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 SARS- CoV-2 infection, however additional follow-up may be needed.
- If the test is positive, then proteins from the viruses that cause COVID-19 or influenza infection have been found in the sample and the individual likely has a respiratory infection with SARS- CoV-2 or influenza.
- 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.
- Based on sequence analysis, a potential for cross-reactivity between the SARS- CoV-2 test and HKU1 exists. Wet testing for HKU1 coronavirus was not conducted and therefore, cross-reactivity between SARS-CoV-2 and HKU1 coronavirus cannot be ruled out.
- Use of OSOM Flu SARS-CoV-2 Combo Test is limited to laboratory personnel and CLIA waived users. Not for home use.
- The contents of this kit are to be used for the qualitative detection of influenza type A and B antigens as well as SARS-CoV-2 antigen from direct anterior nasal swab samples only.
- This test detects viable (live) and non-viable influenza A, influenza B, and SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture or molecular results performed on the same sample.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
- Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
- Test results must be evaluated in conjunction with other clinical data available to the physician.
- Positive test results do not rule out co-infections with other pathogens.
- Positive test results do not identify specific influenza A subtypes, influenza B lineages, or SARS-CoV-2 variants.
- Negative test results cannot rule out diseases caused by other bacterial or viral pathogens.
- Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more likely during periods of low viral activity when prevalence is moderate to low.
- Individuals who received nasally administered influenza vaccine may have positive test results for up to 3 days after vaccination.
- Monoclonal antibodies may fail to detect, or detect with less sensitivity, influenza viruses that have undergone minor amino acid changes in the target epitope region.
- If the differentiation of specific influenza A, influenza B, or SARS subtypes or variants is needed, additional testing, in consultation with state or local public health departments, is required.

## CONDITIONS OF AUTHORIZATION FOR THE LABORATORY AND PATIENT CARE SETTINGS

The OSOM Flu SARS-CoV-2 Combo Test Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>

However, to assist in using the OSOM Flu SARS-CoV-2 Combo Test (“your product” in the conditions below), the relevant Conditions of Authorization are listed below:

- Authorized laboratories\* using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating this labeling may be used, which may include mass media.
- Authorized laboratories using your product must use your product as outlined in OSOM Flu SARS-CoV-2 Combo Test Instructions for Use and Quick Reference Guide. Deviations from the authorized procedures, including authorized instruments, authorized clinical specimen types, authorized control materials, authorized ancillary reagents and authorized materials required to use your product are not permitted.
- Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- 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.
- Authorized laboratories must collect information on the performance of your product and report any significant deviations from the established performance characteristics of your product of which they become aware to DMD/OHT7-OIR/OPEQ/CDRH (via email: [CDRH-EUA-Reporting@fda.hhs.gov](mailto:CDRH-EUA-Reporting@fda.hhs.gov)) and SEKISUI Diagnostics by contacting Technical Services (via email at [techservices@sekisuidiagnostics.com](mailto:techservices@sekisuidiagnostics.com) or via phone at (800) 332-1042).
- 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.
- SEKISUI Diagnostics, authorized distributors, and authorized laboratories using your product must 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.

\*The Letter of Authorization refers to “Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate complexity, high complexity, or waived 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”.

# PERFORMANCE CHARACTERISTICS

## ANALYTICAL PERFORMANCE

### *Limit of Detection (Analytical Sensitivity)*

The limit of detection (LoD) for the OSOM Flu SARS-CoV-2 Combo Test was established using dilutions of one SARS-Related Coronavirus 2 (SARS-CoV-2) Lineage BA.5 Omicron Variant strain (Zeptomatrix Catalog number 0810658CFHI), two influenza A strains (Influenza A H1N1: Influenza A/Michigan/45/15, Influenza A H3N2: Influenza A/Singapore/INFIMH-16-0019/2016) and four influenza B strains (Influenza B/Colorado/6/2017, Influenza B/Phuket/3073/13, Influenza B/Brisbane/35/18, Influenza B/Florida/02/06) in negative clinical matrix. The isolate dilutions were tested by adding fifty (50)  $\mu$ L to the head of the nasal swab and extracting the swab per the OSOM Flu SARS-CoV-2 Combo Test Instructions for Use.

In this study, range finding testing was followed by final dilution testing to determine the LoD of the assay. Range finding involved testing a series of 10-fold dilutions in replicates of three (3) to determine the starting point for the dilution series to determine LoD. The dilution of each virus which resulted in the lowest concentration that generated 100% positive detection rate was set as the target for the next dilution series, which involved testing three (3) replicates of two (2)-fold dilutions. In the final dilution testing, the lowest concentration that generated  $\geq 95\%$  positive detection rate was set as the LoD concentration. Confirmatory testing was done on 3 different days, totaling forty (40) replicates per lot of test sticks.

| <b>Virus Strains</b>                             | <b>Stock Concentration (TCID<sub>50</sub>/mL)</b> | <b>LoD concentration (TCID<sub>50</sub>/mL)</b> | <b>TCID<sub>50</sub>/ Swab</b> | <b># Positive/ # Total Tested</b> | <b>Percent Detected (%)</b> |
|--------------------------------------------------|---------------------------------------------------|-------------------------------------------------|--------------------------------|-----------------------------------|-----------------------------|
| SARS-CoV-2 BA.5 Omicron Variant                  | $6.15 \times 10^6$                                | $3.08 \times 10^4$                              | 1540                           | 80/80                             | 100%                        |
| Influenza A/ Michigan/45/15 (H1N1)               | $1.41 \times 10^5$                                | $3.53 \times 10^2$                              | 17.7                           | 78/80                             | 97.5%                       |
| Influenza A/ Singapore/ INFIMH-16-0019/16 (H3N2) | $3.6 \times 10^6$                                 | $1.58 \times 10^4$                              | 790                            | 79/80                             | 98.8%                       |
| Influenza B/ Phuket/3073/13 (Yamagata)           | $1.86 \times 10^4$                                | $9.3 \times 10^1$                               | 4.7                            | 80/80                             | 100%                        |
| Influenza B/ Colorado/06/17 (Victoria)           | $1.41 \times 10^5$                                | $2.82 \times 10^2$                              | 14.1                           | 80/80                             | 100%                        |
| Influenza B/ Brisbane/35/18 (Victoria)           | $1.15 \times 10^7$                                | $2.30 \times 10^4$                              | 1150                           | 80/80                             | 100%                        |
| Influenza B/ Florida/02/06 (Victoria)            | $1.15 \times 10^7$                                | $2.30 \times 10^4$                              | 1150                           | 80/80                             | 100%                        |

## Analytical Reactivity

The analytical reactivity of the monoclonal antibodies targeting SARS-CoV-2 in the OSOM Flu SARS-CoV-2 Combo Test were evaluated with the currently available SARS-CoV-2 strains and influenza strains using a dilution series. Concentrations listed in the table below indicate the lowest detectable concentrations for which all replicates were positive.

| Strain                                    | Concentration | Concentration Units    |
|-------------------------------------------|---------------|------------------------|
| A/St.Petersburg/61/2015                   | 2.3E+06       | CEID <sub>50</sub> /mL |
| A/Massachusetts/15/2013                   | 8.0E+06       | CEID <sub>50</sub> /mL |
| A/Bangladesh/3002/2015                    | 3.3E+05       | CEID <sub>50</sub> /mL |
| A/Hawaii/66/2019                          | 3.7E+07       | CEID <sub>50</sub> /mL |
| A/Wisconsin/588/2019                      | 2.8E+04       | FFU/mL                 |
| A/Indiana/02/2020                         | 9.7E+06       | CEID <sub>50</sub> /mL |
| A/Dominican Republic/7293/2013            | 5.0E+03       | TCID <sub>50</sub> /mL |
| A/Iowa/53/2015                            | 2.9E+05       | CEID <sub>50</sub> /mL |
| A/Idaho/07/2018                           | 3.2E+02       | TCID <sub>50</sub> /mL |
| A/California/04/2009                      | 3.5E+03       | TCID <sub>50</sub> /mL |
| A/Brisbane/10/2007                        | 8.0E+05       | CEID <sub>50</sub> /mL |
| A/Perth/16/2009                           | 5.5E+05       | CEID <sub>50</sub> /mL |
| A/Victoria/361/2011                       | 6E+05         | CEID <sub>50</sub> /mL |
| A/Texas/50/2012                           | 1.8E+04       | TCID <sub>50</sub> /mL |
| A/Tasmania/503/2020                       | 3.3E+05       | FFU/mL                 |
| A/Indiana/08/2011                         | 4.1E+03       | TCID <sub>50</sub> /mL |
| A/Ohio/09/2015                            | 3.5E+06       | CEID <sub>50</sub> /mL |
| A/Minnesota/19/2011                       | 1.6E+07       | CEID <sub>50</sub> /mL |
| A/northern pintail/Illinois/10OS3959/2010 | 1.4E+06       | CEID <sub>50</sub> /mL |
| A/mallard/Wisconsin/2576/2009             | 1.6E+06       | CEID <sub>50</sub> /mL |
| B/Brisbane/60/2008                        | 1E+05         | CEID <sub>50</sub> /mL |
| B/Colorado/6/2017                         | 4.0E+05       | CEID <sub>50</sub> /mL |
| B/Texas/06/2011                           | 4.0E+06       | CEID <sub>50</sub> /mL |
| B/Wisconsin/1/10                          | 1.41E+02      | TCID <sub>50</sub> /mL |
| B/Lee/1940                                | 4.5E+04       | CEID <sub>50</sub> /mL |
| B/Malaysia/2506/2004                      | 3.0E+03       | CEID <sub>50</sub> /mL |

| Strain                                                          | Concentration | Concentration Units    |
|-----------------------------------------------------------------|---------------|------------------------|
| Isolate hCoV-19/USA/ MD-HP05285/2021 (Delta variant)            | 6.65E+05      | GC/mL                  |
| hCoV-19/USA/MD-HP40900/2022, (Lineage XBB.1.5; Omicron Variant) | 8E+01         | TCID <sub>50</sub> /mL |

## Analytical Specificity: Cross-Reactivity and Microbial Interference

Cross-reactivity and microbial interference with related pathogens, high prevalence disease agents, and normal or pathogenic flora that are reasonably likely to be encountered in the clinical specimen were evaluated with OSOM Flu SARS-CoV-2

Combo Test. Each organism was tested in replicates of five (5) at the concentration listed in the following table of test results.

For cross reactivity, the organisms listed below were tested in negative samples. Testing showed no evidence of cross-reactivity at the concentrations tested.

*In silico* analysis using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) was conducted to assess the degree of protein sequence homology for the following: *Pneumocystis jirovecii*, *Mycobacterium tuberculosis*, Human coronavirus HKU1 N protein, and human SARS coronavirus N protein.

- No significant protein homology was found between the nucleocapsid protein sequences of Human coronavirus HKU1 compared to Influenza A or Influenza B nucleocapsid proteins.
- No significant protein homology was found between the nucleocapsid protein sequences of SARS Coronavirus compared to Influenza A or Influenza B nucleocapsid proteins.
- The comparison between the SARS-CoV-2 N protein and Human coronavirus HKU1 N protein revealed low homology of 30.2% identity across 100% of the full sequences, but cross-reactivity cannot be ruled out.
- The comparison between the SARS-CoV-2 N protein and human SARS coronavirus N protein revealed significant homology of 90.5% identity across 100% of the full sequences, but cross-reactivity cannot be ruled out.
- No significant protein homology was found between the nucleocapsid protein sequences of Human coronavirus HKU1 compared to Influenza A or Influenza B nucleocapsid proteins.
- No significant protein homology was found between the nucleocapsid protein sequences of SARS Coronavirus compared to Influenza A or Influenza B nucleocapsid proteins.

| Microorganism Introduced | Concentration                                 | Influenza A Test Results (positive/total) | Influenza B Test Results (positive/total) | SARS-CoV-2 Test Results (positive/total) |
|--------------------------|-----------------------------------------------|-------------------------------------------|-------------------------------------------|------------------------------------------|
| NCM in Saline Only       | N/A                                           | 0/5                                       | 0/5                                       | 0/5                                      |
| Human coronavirus 229E   | 1.43 x 10 <sup>5</sup> TCID <sub>50</sub> /mL | 0/5                                       | 0/5                                       | 0/5                                      |
| Human coronavirus OC43   | 1.43 x 10 <sup>5</sup> TCID <sub>50</sub> /mL | 0/5                                       | 0/5                                       | 0/5                                      |
| Human coronavirus NL63   | 1.43 x 10 <sup>5</sup> TCID <sub>50</sub> /mL | 0/5                                       | 0/5                                       | 0/5                                      |
| MERS-coronavirus         | 1.43 x 10 <sup>5</sup> TCID <sub>50</sub> /mL | 0/5                                       | 0/5                                       | 0/5                                      |
| Rhinovirus Type 1A       | 1.43 x 10 <sup>5</sup> TCID <sub>50</sub> /mL | 0/5                                       | 0/5                                       | 0/5                                      |
| Influenza A (H1N1)*      | 7.05 x 10 <sup>4</sup> TCID <sub>50</sub> /mL | N/A                                       | 0/5                                       | 0/5                                      |
| Influenza A (H3N2)       | 1.43 x 10 <sup>5</sup> TCID <sub>50</sub> /mL | N/A                                       | 0/5                                       | 0/5                                      |
| Influenza B (Victoria)   | 1.43 x 10 <sup>5</sup> TCID <sub>50</sub> /mL | 0/5                                       | N/A                                       | 0/5                                      |
| Influenza B (Yamagata)*  | 9.30 x 10 <sup>3</sup> TCID <sub>50</sub> /mL | 0/5                                       | N/A                                       | 0/5                                      |

\* Recommended testing concentrations were not achievable due to the low vial concentrations. The samples were tested undiluted.

| <b>Microorganism Introduced</b>                   | <b>Concentration</b>                          | <b>Influenza A Test Results (positive/total)</b> | <b>Influenza B Test Results (positive/total)</b> | <b>SARS-CoV-2 Test Results (positive/total)</b> |
|---------------------------------------------------|-----------------------------------------------|--------------------------------------------------|--------------------------------------------------|-------------------------------------------------|
| Parainfluenza virus 1                             | 1.00 x 10 <sup>5</sup> U/mL                   | 0/5                                              | 0/5                                              | 0/5                                             |
| Parainfluenza virus 2                             | 1.43 x 10 <sup>5</sup> TCID <sub>50</sub> /mL | 0/5                                              | 0/5                                              | 0/5                                             |
| Parainfluenza virus 3                             | 1.43 x 10 <sup>5</sup> TCID <sub>50</sub> /mL | 0/5                                              | 0/5                                              | 0/5                                             |
| Parainfluenza virus 4A                            | 1.00 x 10 <sup>5</sup> U/mL                   | 0/5                                              | 0/5                                              | 0/5                                             |
| <i>Staphylococcus aureus</i> (Protein A producer) | 1.00 x 10 <sup>6</sup> CFU/mL                 | 0/5                                              | 0/5                                              | 0/5                                             |
| Cytomegalovirus*                                  | 7.05 x 10 <sup>4</sup> TCID <sub>50</sub> /mL | 0/5                                              | 0/5                                              | 0/5                                             |
| Coxsackievirus                                    | 1.00 x 10 <sup>5</sup> U/mL                   | 0/5                                              | 0/5                                              | 0/5                                             |
| Measles                                           | 1.43 x 10 <sup>5</sup> TCID <sub>50</sub> /mL | 0/5                                              | 0/5                                              | 0/5                                             |
| <i>Corynebacterium diphtheriae</i>                | 1.00 x 10 <sup>6</sup> CFU/mL                 | 0/5                                              | 0/5                                              | 0/5                                             |
| <i>Lactobacillus acidophilus</i>                  | 1.00 x 10 <sup>6</sup> CFU/mL                 | 0/5                                              | 0/5                                              | 0/5                                             |
| <i>Mycobacterium tuberculosis</i> (avirulent)     | 1.00 x 10 <sup>6</sup> CFU/mL                 | 0/5                                              | 0/5                                              | 0/5                                             |
| <i>Neisseria gonorrhoeae</i>                      | 1.00 x 10 <sup>6</sup> CFU/mL                 | 0/5                                              | 0/5                                              | 0/5                                             |
| <i>Streptococcus pneumoniae</i>                   | 1.00 x 10 <sup>6</sup> CFU/mL                 | 0/5                                              | 0/5                                              | 0/5                                             |
| <i>Streptococcus salivarius</i>                   | 1.00 x 10 <sup>6</sup> CFU/mL                 | 0/5                                              | 0/5                                              | 0/5                                             |
| Adenovirus Type 1                                 | 1.00 x 10 <sup>5</sup> U/mL                   | 0/5                                              | 0/5                                              | 0/5                                             |
| Adenovirus Type 7                                 | 1.00 x 10 <sup>5</sup> U/mL                   | 0/5                                              | 0/5                                              | 0/5                                             |
| Human Metapneumovirus (hMPV)                      | 1.43 x 10 <sup>5</sup> TCID <sub>50</sub> /mL | 0/5                                              | 0/5                                              | 0/5                                             |
| <i>Enterovirus</i> *                              | 8.5 x 10 <sup>4</sup> TCID <sub>50</sub> /mL  | 0/5                                              | 0/5                                              | 0/5                                             |
| Respiratory syncytial virus Type B                | 1.43 x 10 <sup>5</sup> TCID <sub>50</sub> /mL | 0/5                                              | 0/5                                              | 0/5                                             |
| <i>Haemophilus influenzae</i>                     | 1.00 x 10 <sup>6</sup> CFU/mL                 | 0/5                                              | 0/5                                              | 0/5                                             |
| <i>Streptococcus pyogenes</i>                     | 1.00 x 10 <sup>6</sup> CFU/mL                 | 0/5                                              | 0/5                                              | 0/5                                             |

\* Recommended testing concentrations were not achievable due to the low vial concentrations. The samples were tested undiluted.

| Microorganism Introduced                                                       | Concentration                                                               | Influenza A Test Results (positive/total) | Influenza B Test Results (positive/total) | SARS-CoV-2 Test Results (positive/total) |
|--------------------------------------------------------------------------------|-----------------------------------------------------------------------------|-------------------------------------------|-------------------------------------------|------------------------------------------|
| <i>Candida albicans</i>                                                        | 1.00 x 10 <sup>6</sup> CFU/mL                                               | 0/5                                       | 0/5                                       | 0/5                                      |
| Pooled human nasal wash – representative of normal respiratory microbial flora | N/A – Pooled Human Nasal Wash was added directly to swabs without dilution. | 0/5                                       | 0/5                                       | 0/5                                      |
| <i>Bordetella pertussis</i>                                                    | 1.00 x 10 <sup>6</sup> CFU/mL                                               | 0/5                                       | 0/5                                       | 0/5                                      |
| <i>Mycoplasma pneumoniae</i>                                                   | 1.00 x 10 <sup>6</sup> CCU/mL                                               | 0/5                                       | 0/5                                       | 0/5                                      |
| <i>Chlamydomphila pneumoniae</i>                                               | 1.00 x 10 <sup>6</sup> IFU/mL                                               | 0/5                                       | 0/5                                       | 0/5                                      |
| <i>Legionella pneumophila</i>                                                  | 1.00 x 10 <sup>6</sup> CFU/mL                                               | 0/5                                       | 0/5                                       | 0/5                                      |
| <i>Staphylococcus epidermidis</i>                                              | 1.00 x 10 <sup>6</sup> CFU/mL                                               | 0/5                                       | 0/5                                       | 0/5                                      |
| Epstein Barr Virus                                                             | 1.00 x 10 <sup>5</sup> cp/mL                                                | 0/5                                       | 0/5                                       | 0/5                                      |
| Human herpes virus                                                             | 1.43 x 10 <sup>5</sup> TCID <sub>50</sub> /mL                               | 0/5                                       | 0/5                                       | 0/5                                      |
| Mumps virus                                                                    | 1.43 x 10 <sup>5</sup> TCID <sub>50</sub> /mL                               | 0/5                                       | 0/5                                       | 0/5                                      |
| <i>Escherichia coli</i>                                                        | 1.00 x 10 <sup>6</sup> CFU/mL                                               | 0/5                                       | 0/5                                       | 0/5                                      |
| <i>Moraxella catarrhalis</i>                                                   | 1.00 x 10 <sup>6</sup> CFU/mL                                               | 0/5                                       | 0/5                                       | 0/5                                      |
| <i>Neisseria meningitidis</i>                                                  | 1.00 x 10 <sup>6</sup> CFU/mL                                               | 0/5                                       | 0/5                                       | 0/5                                      |
| <i>Pseudomonas aeruginosa</i>                                                  | 1.00 x 10 <sup>6</sup> CFU/mL                                               | 0/5                                       | 0/5                                       | 0/5                                      |
| <i>Klebsiella pneumoniae</i>                                                   | 1.00 x 10 <sup>6</sup> CFU/mL                                               | 0/5                                       | 0/5                                       | 0/5                                      |

\* Recommended testing concentrations were not achievable due to the low vial concentrations. The samples were tested undiluted.

### Microbial interference

For evaluating microbial interference against the SARS-CoV-2, Influenza A (H1N1), Influenza B (Victoria) test lines, the organisms were tested with SARS-CoV-2 heat-inactivated isolate BA.5 Omicron Variant (Zeptomatrix Catalog number 0810658CFHI), Influenza A/Michigan/45/2015 (ZeptoMetrix PN 0810538CF) or Influenza B/Florida/02/06 (ZeptoMetrix PN 0810037CF) diluted to 2x LoD concentration in negative clinical matrix. No cross reactivity was seen with the organisms tested at the concentrations shown below.



| <b>Microorganism Introduced</b>                   | <b>Microorganism Concentration</b>            | <b>Influenza A Test Results (positive/total)</b> | <b>Influenza B Test Results (positive/total)</b> | <b>SARS-CoV-2 Test Results (positive/total)</b> |
|---------------------------------------------------|-----------------------------------------------|--------------------------------------------------|--------------------------------------------------|-------------------------------------------------|
| NCM in Saline Only                                | N/A                                           | 5/5                                              | 5/5                                              | 5/5                                             |
| Human coronavirus 229E                            | 1.43 x 10 <sup>5</sup> TCID <sub>50</sub> /mL | 5/5                                              | 5/5                                              | 5/5                                             |
| Human coronavirus OC43                            | 1.43 x 10 <sup>5</sup> TCID <sub>50</sub> /mL | 5/5                                              | 5/5                                              | 5/5                                             |
| Human coronavirus NL63                            | 1.43 x 10 <sup>5</sup> TCID <sub>50</sub> /mL | 5/5                                              | 5/5                                              | 5/5                                             |
| MERS-coronavirus                                  | 1.43 x 10 <sup>5</sup> TCID <sub>50</sub> /mL | 5/5                                              | 5/5                                              | 5/5                                             |
| Rhinovirus Type 1A                                | 1.43 x 10 <sup>5</sup> TCID <sub>50</sub> /mL | 5/5                                              | 5/5                                              | 5/5                                             |
| Influenza A (H1N1)*                               | 7.05 x 10 <sup>4</sup> TCID <sub>50</sub> /mL | 5/5                                              | 5/5                                              | 5/5                                             |
| Influenza A (H3N2)                                | 1.43 x 10 <sup>5</sup> TCID <sub>50</sub> /mL | 5/5                                              | 5/5                                              | 5/5                                             |
| Influenza B (Victoria)                            | 1.43 x 10 <sup>5</sup> TCID <sub>50</sub> /mL | 5/5                                              | 5/5                                              | 5/5                                             |
| Influenza B (Yamagata)*                           | 9.30 x 10 <sup>3</sup> TCID <sub>50</sub> /mL | 5/5                                              | 5/5                                              | 5/5                                             |
| Parainfluenza virus 1                             | 1.00 x 10 <sup>5</sup> U/mL                   | 5/5                                              | 5/5                                              | 5/5                                             |
| Parainfluenza virus 2                             | 1.43 x 10 <sup>5</sup> TCID <sub>50</sub> /mL | 5/5                                              | 5/5                                              | 5/5                                             |
| Parainfluenza virus 3                             | 1.43 x 10 <sup>5</sup> TCID <sub>50</sub> /mL | 5/5                                              | 5/5                                              | 5/5                                             |
| Parainfluenza virus 4A                            | 1.00 x 10 <sup>5</sup> U/mL                   | 5/5                                              | 5/5                                              | 5/5                                             |
| <i>Staphylococcus aureus</i> (Protein A producer) | 1.00 x 10 <sup>6</sup> CFU/mL                 | 5/5                                              | 5/5                                              | 5/5                                             |
| Cytomegalovirus*                                  | 7.05 x 10 <sup>4</sup> TCID <sub>50</sub> /mL | 5/5                                              | 5/5                                              | 5/5                                             |
| Coxsackievirus                                    | 1.00 x 10 <sup>5</sup> U/mL                   | 5/5                                              | 5/5                                              | 5/5                                             |
| Measles                                           | 1.43 x 10 <sup>5</sup> TCID <sub>50</sub> /mL | 5/5                                              | 5/5                                              | 5/5                                             |
| <i>Corynebacterium diphtheriae</i>                | 1.00 x 10 <sup>6</sup> CFU/mL                 | 5/5                                              | 5/5                                              | 5/5                                             |
| <i>Lactobacillus acidophilus</i>                  | 1.00 x 10 <sup>6</sup> CFU/mL                 | 5/5                                              | 5/5                                              | 5/5                                             |
| <i>Mycobacterium tuberculosis</i> (avirulent)     | 1.00 x 10 <sup>6</sup> CFU/mL                 | 5/5                                              | 5/5                                              | 5/5                                             |
| <i>Neisseria gonorrhoeae</i>                      | 1.00 x 10 <sup>6</sup> CFU/mL                 | 5/5                                              | 5/5                                              | 5/5                                             |

\* Recommended testing concentrations were not achievable due to the low vial concentrations. The samples were tested undiluted.

| Microorganism Introduced                                                       | Microorganism Concentration                                                 | Influenza A Test Results (positive/total) | Influenza B Test Results (positive/total) | SARS-CoV-2 Test Results (positive/total) |
|--------------------------------------------------------------------------------|-----------------------------------------------------------------------------|-------------------------------------------|-------------------------------------------|------------------------------------------|
| <i>Streptococcus pneumoniae</i>                                                | 1.00 x 10 <sup>6</sup> CFU/mL                                               | 5/5                                       | 5/5                                       | 5/5                                      |
| <i>Streptococcus salivarius</i>                                                | 1.00 x 10 <sup>6</sup> CFU/mL                                               | 5/5                                       | 5/5                                       | 5/5                                      |
| Adenovirus Type 1                                                              | 1.00 x 10 <sup>5</sup> U/mL                                                 | 5/5                                       | 5/5                                       | 5/5                                      |
| Adenovirus Type 7                                                              | 1.00 x 10 <sup>5</sup> U/mL                                                 | 5/5                                       | 5/5                                       | 5/5                                      |
| Human Metapneumovirus (hMPV)                                                   | 1.43 x 10 <sup>5</sup> TCID <sub>50</sub> /mL                               | 5/5                                       | 5/5                                       | 5/5                                      |
| Enterovirus*                                                                   | 8.5 x 10 <sup>4</sup> TCID <sub>50</sub> /mL                                | 5/5                                       | 5/5                                       | 5/5                                      |
| Respiratory syncytial virus Type B                                             | 1.43 x 10 <sup>5</sup> TCID <sub>50</sub> /mL                               | 5/5                                       | 5/5                                       | 5/5                                      |
| <i>Haemophilus influenzae</i>                                                  | 1.00 x 10 <sup>6</sup> CFU/mL                                               | 5/5                                       | 5/5                                       | 5/5                                      |
| <i>Streptococcus pyogenes</i>                                                  | 1.00 x 10 <sup>6</sup> CFU/mL                                               | 5/5                                       | 5/5                                       | 5/5                                      |
| <i>Candida albicans</i>                                                        | 1.00 x 10 <sup>6</sup> CFU/mL                                               | 5/5                                       | 5/5                                       | 5/5                                      |
| Pooled human nasal wash – representative of normal respiratory microbial flora | N/A – Pooled Human Nasal Wash was added directly to swabs without dilution. | 5/5                                       | 5/5                                       | 5/5                                      |
| <i>Bordetella pertussis</i>                                                    | 1.00 x 10 <sup>6</sup> CFU/mL                                               | 5/5                                       | 5/5                                       | 5/5                                      |
| <i>Mycoplasma pneumoniae</i>                                                   | 1.00 x 10 <sup>6</sup> CCU/mL                                               | 5/5                                       | 5/5                                       | 5/5                                      |
| <i>Chlamydia pneumoniae</i>                                                    | 1.00 x 10 <sup>6</sup> IFU/mL                                               | 5/5                                       | 5/5                                       | 5/5                                      |
| <i>Legionella pneumophila</i>                                                  | 1.00 x 10 <sup>6</sup> CFU/mL                                               | 5/5                                       | 5/5                                       | 5/5                                      |
| <i>Staphylococcus epidermidis</i>                                              | 1.00 x 10 <sup>6</sup> CFU/mL                                               | 5/5                                       | 5/5                                       | 5/5                                      |
| Epstein Barr Virus                                                             | 1.00 x 10 <sup>5</sup> cp/mL                                                | 5/5                                       | 5/5                                       | 5/5                                      |
| Human herpes virus                                                             | 1.43 x 10 <sup>5</sup> TCID <sub>50</sub> /mL                               | 5/5                                       | 5/5                                       | 5/5                                      |
| Mumps virus                                                                    | 1.43 x 10 <sup>5</sup> TCID <sub>50</sub> /mL                               | 5/5                                       | 5/5                                       | 5/5                                      |
| <i>Escherichia coli</i>                                                        | 1.00 x 10 <sup>6</sup> CFU/mL                                               | 5/5                                       | 5/5                                       | 5/5                                      |
| <i>Moraxella catarrhalis</i>                                                   | 1.00 x 10 <sup>6</sup> CFU/mL                                               | 5/5                                       | 5/5                                       | 5/5                                      |

\* Recommended testing concentrations were not achievable due to the low vial concentrations. The samples were tested undiluted.

| Microorganism Introduced      | Microorganism Concentration   | Influenza A Test Results (positive/total) | Influenza B Test Results (positive/total) | SARS-CoV-2 Test Results (positive/total) |
|-------------------------------|-------------------------------|-------------------------------------------|-------------------------------------------|------------------------------------------|
| <i>Neisseria meningitidis</i> | 1.00 x 10 <sup>6</sup> CFU/mL | 5/5                                       | 5/5                                       | 5/5                                      |
| <i>Pseudomonas aeruginosa</i> | 1.00 x 10 <sup>6</sup> CFU/mL | 5/5                                       | 5/5                                       | 5/5                                      |
| <i>Klebsiella pneumoniae</i>  | 1.00 x 10 <sup>6</sup> CFU/mL | 5/5                                       | 5/5                                       | 5/5                                      |

\* Recommended testing concentrations were not achievable due to the low vial concentrations. The samples were tested undiluted.

### Endogenous Interfering Substances

A total of twenty nine (29) potentially interfering substances, either naturally present in respiratory specimens or artificially introduced into the nasal cavity or nasopharynx, were tested to evaluate the susceptibility of the OSOM Flu SARS-CoV-2 Combo Test to interference when elevated levels of these substances were added to the nasal swab head in the absence (negative) and presence (positive) of SARS-CoV-2, two different strains of influenza A, or two different strains of influenza B. Each substance was tested in replicates of five (5). No interference was observed for any of the substances at the concentration listed below, that is all 5 replicates were negative for each tested substance.

| Interfering Substance Introduced                  | Concentration                | Interference (Yes/No) |
|---------------------------------------------------|------------------------------|-----------------------|
| Control (NCM in Saline only)                      | N/A                          | No                    |
| Chloraseptic (Menthol/ Benzocaine) Throat Lozenge | 3 mg/mL                      | No                    |
| Sore Throat Spray (Phenol Oral Anesthetic)        | 5% w/v                       | No                    |
| Mucin                                             | 2.5 mg/mL                    | No                    |
| Whole Blood                                       | 5%                           | No                    |
| Leukocytes                                        | 5 x 10 <sup>6</sup> cells/mL | No                    |
| Nasal drops (Phenylephrine)                       | 15% v/v                      | No                    |
| NasalCrom (Cromolyn)                              | 15% v/v                      | No                    |
| Afrin (Oxymetazoline)                             | 15% v/v                      | No                    |
| Saline Nasal Spray                                | 15% v/v                      | No                    |
| Beclomethasone                                    | 15% v/v                      | No                    |
| Dexamethasone                                     | 15% v/v                      | No                    |
| Flunisolide                                       | 15% v/v                      | No                    |
| Triamcinolone                                     | 15% v/v                      | No                    |
| Budesonide                                        | 15% v/v                      | No                    |
| Mometasone                                        | 15% v/v                      | No                    |
| Nasal spray (Fluticasone Propionate)              | 15% v/v                      | No                    |
| NasoGEL                                           | 5% v/v                       | No                    |
| Nasal spray (Zicam)                               | 15% v/v                      | No                    |
| Nasal wash (Alkalol)                              | 15% v/v                      | No                    |
| Tamiflu (Oseltamivir Phosphate)                   | 5 mg/mL                      | No                    |
| Remdesivir                                        | 5 mg/mL                      | No                    |
| Molnupiravir                                      | 5 mg/mL                      | No                    |
| Zanamivir                                         | 5.5 mg/mL                    | No                    |
| Mupirocin Ointment                                | 7.5 mg/mL                    | No                    |

| Interfering Substance Introduced   | Concentration | Interference (Yes/No) |
|------------------------------------|---------------|-----------------------|
| Mupirocin powder                   | 10 mg/mL      | No                    |
| Tobramycin                         | 1.25 mg/mL    | No                    |
| Hand Sanitizer with Aloe           | 5%            | No                    |
| Hand Sanitizer Lotion (Vaseline)   | 10%           | No                    |
| Liquid Hand Sanitizer (NatureWell) | 15%           | No                    |
| Hand Soap Liquid Gel (Softsoap)    | 10%           | No                    |

### High Dose Hook Effect

No high-dose hook effect was observed with the OSOM Flu SARS-CoV-2 Combo Test when testing high concentrations of SARS-CoV-2, Influenza A or Influenza B strains.

| Viral Strain Tested                    | Concentration (TCID <sub>50</sub> /mL)        |
|----------------------------------------|-----------------------------------------------|
| Influenza A/Michigan/45/15 (H1N1)      | 1.41 x 10 <sup>5</sup> TCID <sub>50</sub> /mL |
| Influenza B/Colorado/6/2017 (Victoria) | 1.41 x 10 <sup>5</sup> TCID <sub>50</sub> /mL |
| SARS-CoV-2 BA.5 Omicron Variant        | 6.15 x 10 <sup>6</sup> TCID <sub>50</sub> /mL |

### Competitive Interference

For co-infection, SARS-CoV-2 at levels near LoD was tested in the presence of high levels of influenza A or influenza B and near LoD influenza A and influenza B in the presence of high levels of SARS-CoV-2. Additionally, the performance of the OSOM ULTRA PLUS FLU A&B Test was evaluated in the presence of high levels of influenza A and influenza B. Contrived high and low titer influenza A (H1N1 and H3N2) and B positive samples were. No competitive interference was observed between SARS-CoV-2 and influenza A and B as listed in the table below.

| Sample | High titer target |                                        | Low titer target       |                                        | Low titer target Percent Positivity |
|--------|-------------------|----------------------------------------|------------------------|----------------------------------------|-------------------------------------|
|        | Virus Name        | Concentration (TCID <sub>50</sub> /mL) | Virus Name             | Concentration (TCID <sub>50</sub> /mL) |                                     |
| 1      | Flu A (H1N1)      | 1.13 x 10 <sup>5</sup>                 | inactivated SARS-Cov-2 | 6.16 x 10 <sup>4</sup>                 | 100%                                |
| 2      | Flu A (H1N1)      | 1.13 x 10 <sup>5</sup>                 | Flu B (Victoria)       | 5.64 x 10 <sup>2</sup>                 | 100%                                |
| 3      | Flu A (H1N1)      | 1.13 x 10 <sup>5</sup>                 | Flu B (Yamagata)       | 1.86 x 10 <sup>2</sup>                 | 100%                                |
| 4      | Flu A (H3N2)      | 1.58 x 10 <sup>6</sup>                 | inactivated SARS-CoV-2 | 6.16 x 10 <sup>4</sup>                 | 100%                                |
| 5      | Flu A (H3N2)      | 1.58 x 10 <sup>6</sup>                 | Flu B (Victoria)       | 5.64 x 10 <sup>2</sup>                 | 100%                                |
| 6      | Flu A (H3N2)      | 1.58 x 10 <sup>6</sup>                 | Flu B (Yamagata)       | 1.86 x 10 <sup>2</sup>                 | 100%                                |
| 7      | Flu B (Victoria)  | 1.13 x 10 <sup>5</sup>                 | inactivated SARS-CoV-2 | 6.16 x 10 <sup>4</sup>                 | 100%                                |
| 8      | Flu B (Victoria)  | 1.13 x 10 <sup>5</sup>                 | Flu A (H1N1)           | 7.06 x 10 <sup>2</sup>                 | 100%                                |
| 9      | Flu B (Victoria)  | 1.13 x 10 <sup>5</sup>                 | Flu A (H3N2)           | 3.16 x 10 <sup>4</sup>                 | 100%                                |
| 10     | Flu B (Yamagata)  | 1.49 x 10 <sup>4</sup>                 | inactivated SARS-CoV-2 | 6.16 x 10 <sup>4</sup>                 | 100%                                |
| 11     | Flu B (Yamagata)  | 1.49 x 10 <sup>4</sup>                 | Flu A (H1N1)           | 7.06 x 10 <sup>2</sup>                 | 100%                                |

| Sample | High titer target      |                                        | Low titer target       |                                                           | Low titer target Percent Positivity |
|--------|------------------------|----------------------------------------|------------------------|-----------------------------------------------------------|-------------------------------------|
|        | Virus Name             | Concentration (TCID <sub>50</sub> /mL) | Virus Name             | Concentration (TCID <sub>50</sub> /mL)                    |                                     |
| 12     | Flu B (Yamagata)       | 1.49 x 10 <sup>4</sup>                 | Flu A (H3N2)           | 3.16 x 10 <sup>4</sup>                                    | 100%                                |
| 13     | inactivated SARS-CoV-2 | 3.08 x 10 <sup>6</sup>                 | Flu A(H1N1)            | 7.06 x 10 <sup>2</sup>                                    | 100%                                |
| 14     | inactivated SARS-CoV-2 | 3.08 x 10 <sup>6</sup>                 | Flu A (H3N2)           | 3.16 x 10 <sup>4</sup>                                    | 100%                                |
| 15     | inactivated SARS-CoV-2 | 3.08 x 10 <sup>6</sup>                 | Flu B (Victoria)       | 5.64 x 10 <sup>2</sup>                                    | 100%                                |
| 16     | inactivated SARS-CoV-2 | 3.08 x 10 <sup>6</sup>                 | Flu B (Yamagata)       | 1.86 x 10 <sup>2</sup>                                    | 100%                                |
| 17     | Flu A (H1N1)           | 1.13 x 10 <sup>5</sup>                 | Flu B (Yamagata) &     | Flu B (Yamagata): 1.86 x 10 <sup>2</sup>                  | 100%                                |
|        |                        |                                        | inactivated SARS-CoV-2 | SARS-CoV-2: 6.16 x 10 <sup>4</sup>                        | 100%                                |
| 18     | Flu A (H3N2)           | 1.58 x 10 <sup>6</sup>                 | Flu B (Victoria) &     | Flu B (Victoria): 5.64 x 10 <sup>2</sup>                  | 100%                                |
|        |                        |                                        | inactivated SARS-CoV-2 | SARS-CoV-2: 6.16 x 10 <sup>4</sup>                        | 100%                                |
| 19     | Flu A (H3N2)           | 1.58 x 10 <sup>6</sup>                 | Flu B (Yamagata) &     | Flu B (Yamagata): 1.86 x 10 <sup>2</sup>                  | 100%                                |
|        |                        |                                        | inactivated SARS-CoV-2 | SARS-CoV-2: 6.16 x 10 <sup>4</sup>                        | 100%                                |
| 20     | Flu B (Victoria)       | 1.13 x 10 <sup>5</sup>                 | Flu A (H1N1) &         | Flu A (H1N1): 7.06 x 10 <sup>2</sup>                      | 100%                                |
|        |                        |                                        | inactivated SARS-CoV-2 | SARS-CoV-2: 6.16 x 10 <sup>4</sup>                        | 100%                                |
| 21     | Flu B (Victoria)       | 1.13 x 10 <sup>5</sup>                 | Flu A (H3N2) &         | Flu A (H3N2): 3.16 x 10 <sup>4</sup>                      | 100%                                |
|        |                        |                                        | inactivated SARS-CoV-2 | SARS-CoV-2: 6.16 x 10 <sup>4</sup> TCID <sub>50</sub> /mL | 100%                                |
| 22     | Flu B (Yamagata)       | 1.49 x 10 <sup>4</sup>                 | Flu A (H1N1) &         | Flu A (H1N1): 7.06 x 10 <sup>2</sup>                      | 100%                                |
|        |                        |                                        | Inactivated SARS-CoV-2 | SARS-CoV-2: 6.16 x 10 <sup>4</sup>                        | 100%                                |
| 23     | Flu B (Yamagata)       | 1.49 x 10 <sup>4</sup>                 | Flu A (H3N2) &         | Flu A (H3N2): 3.16 x 10 <sup>4</sup>                      | 100%                                |
|        |                        |                                        | Inactivated SARS-CoV-2 | SARS-CoV-2: 6.16 x 10 <sup>4</sup>                        | 100%                                |

| Sample | High titer target      |                                        | Low titer target |                                             | Low titer target Percent Positivity |
|--------|------------------------|----------------------------------------|------------------|---------------------------------------------|-------------------------------------|
|        | Virus Name             | Concentration (TCID <sub>50</sub> /mL) | Virus Name       | Concentration (TCID <sub>50</sub> /mL)      |                                     |
| 24     | Inactivated SARS-CoV-2 | 3.08 x 10 <sup>6</sup>                 | Flu A (H1N1) &   | Flu A (H1N1):<br>7.06 x 10 <sup>2</sup>     | 100%                                |
|        |                        |                                        | Flu B (Victoria) | Flu B (Victoria):<br>5.64 x 10 <sup>2</sup> | 100%                                |
| 25     | Inactivated SARS-CoV-2 | 3.08 x 10 <sup>6</sup>                 | Flu A (H1N1) &   | Flu A (H1N1):<br>7.06 x 10 <sup>2</sup>     | 100%                                |
|        |                        |                                        | Flu B (Yamagata) | Flu B (Yamagata):<br>1.86 x 10 <sup>2</sup> | 100%                                |
| 26     | Inactivated SARS-CoV-2 | 3.08 x 10 <sup>6</sup>                 | Flu A (H3N2) &   | Flu A (H3N2):<br>3.16 x 10 <sup>4</sup>     | 100%                                |
|        |                        |                                        | Flu B (Victoria) | Flu B (Victoria):<br>5.64 x 10 <sup>2</sup> | 100%                                |
| 27     | Inactivated SARS-CoV-2 | 3.08 x 10 <sup>6</sup>                 | Flu A (H3N2) &   | Flu A (H3N2):<br>3.16 x 10 <sup>4</sup>     | 100%                                |
|        |                        |                                        | Flu B (Yamagata) | Flu B (Yamagata):<br>1.86 x 10 <sup>2</sup> | 100%                                |

## CLINICAL PERFORMANCE

A prospective clinical study to establish the performance characteristics of the OSOM Flu SARS-CoV-2 Combo Test was conducted with specimens prospectively collected from October 2023 to January 2024 at seven (7) sites across the United States. Subjects performed testing on self-collected swab samples in age groups 14 and older, and adult collected samples for age groups 2-13, in a simulated at-home environment, with the exception of 2 cases.

Samples were collected from individuals with associated symptoms of respiratory infection, who provided informed consent. Two (2) nasal swabs were collected from each subject according to standard collection methods. One (1) nasal swab was self-collected and used for immediate testing with the OSOM Flu SARS-CoV-2 Combo Test per the test procedure. The other nasal swab sample was collected by a healthcare professional in VTM, at least 15 minutes after each subject/tester completed sample collection and testing on the investigational test. The HCP collected specimens were sent for testing by the reference methods, FDA-cleared molecular comparator tests, within the allowable time frames of specimen collection per the product instructions.

Nasal swab specimens were collected from 726 subjects enrolled in the prospective clinical study. Of those, 23 swab samples were unevaluable due to eligibility criteria, candidate device invalid, or reference sample handling issues, leaving a total of 703 evaluable samples for the SARS-CoV-2 performance evaluation. In addition, 4 swab samples were not evaluable due to reference results not being available, leaving a total of 699 evaluable samples for the Flu A/B performance evaluation.

## SUBJECTS DEMOGRAPHICS

### *Subject demographics*

|                                   | Subjects (by lay-user collection and testing (N=61)) | Self-collecting and testing (N=642) | Overall (N=703) |
|-----------------------------------|------------------------------------------------------|-------------------------------------|-----------------|
| <b>Age</b>                        |                                                      |                                     |                 |
| Mean (SD)                         | 8.9 (2.7)                                            | 38.7 (14.7)                         | 36.1 (16.4)     |
| Median [Min, Max]                 | 9 [ 3, 14]                                           | 37 [14, 85]                         | 35 [3, 85]      |
| <b>Age Group</b>                  |                                                      |                                     |                 |
| ≥2-<14 years of age               | 59 (96.7%)                                           | 0 (0.0%)                            | 59 (8.4%)       |
| 14-21 years of age                | 2 (3.3%)                                             | 65 (10.1%)                          | 67 (9.5%)       |
| 22-64 years of age                | 0 (0.0%)                                             | 548 (85.4%)                         | 548 (78.0%)     |
| ≥65 years of age                  | 0 (0.0%)                                             | 29 (4.5%)                           | 29 (4.1%)       |
| <b>Sex at Birth</b>               |                                                      |                                     |                 |
| Female                            | 31 (50.8%)                                           | 410 (63.9%)                         | 441 (62.7%)     |
| Male                              | 30 (49.2%)                                           | 232 (36.1%)                         | 262 (37.3%)     |
| <b>Ethnicity</b>                  |                                                      |                                     |                 |
| Hispanic/Latino                   | 38 (62.3%)                                           | 241 (37.5%)                         | 279 (39.7%)     |
| Not Hispanic/Latino               | 23 (37.7%)                                           | 401 (62.5%)                         | 424 (60.3%)     |
| <b>Race</b>                       |                                                      |                                     |                 |
| American Indian or Alaskan Native | 0 (0.0%)                                             | 3 (0.5%)                            | 3 (0.4%)        |
| Asian                             | 0 (0.0%)                                             | 13 (2.0%)                           | 13 (1.8%)       |
| Black or African American         | 6 (9.8%)                                             | 64 (10.0%)                          | 70 (10.0%)      |
| Native Hawaiian/Pacific Islander  | 0 (0.0%)                                             | 1 (0.2%)                            | 1 (0.1%)        |
| White                             | 51 (83.6%)                                           | 538 (83.8%)                         | 589 (83.8%)     |

Subject demographics

|                              | Subjects (by lay-user collection and testing (N=61)) | Self-collecting and testing (N=642) | Overall (N=703) |
|------------------------------|------------------------------------------------------|-------------------------------------|-----------------|
| Unknown/Prefer not to answer | 0 (0.0%)                                             | 10 (1.6%)                           | 10 (1.4%)       |
| Other (Mixed race/biracial)  | 4 (6.6%)                                             | 13 (2.0%)                           | 17 (2.4%)       |

## SARS-COV-2 PERFORMANCE

Investigational Test results for SARS-CoV-2 vs. FDA-cleared molecular test

| SARS-CoV-2                | Comparators Positives | Comparators Negatives | Sum        |
|---------------------------|-----------------------|-----------------------|------------|
| Investigational Positives | 86                    | 5                     | 91         |
| Investigational Negatives | 58                    | 554                   | 612        |
| <b>Sum</b>                | <b>144</b>            | <b>559</b>            | <b>703</b> |

Positive Percent Agreement =  $(86/144) = 59.7\%$  (95% CI: 51.6%-67.4%)

Negative Percent Agreement =  $(554/559) = 99.1\%$  (95% CI: 97.9%-99.6%)

## Controlled Analysis

Controlled Analysis for SARS-CoV-2

|                                               | All Study Cohort | 10% Low Positives | 12.5% Low Positives | 15% Low Positives | 17.5% Low Positives | 20% Low Positives |
|-----------------------------------------------|------------------|-------------------|---------------------|-------------------|---------------------|-------------------|
| High Positive Samples                         | 82               | 82                | 82                  | 82                | 82                  | 82                |
| Low Positive Samples                          | 62               | 10                | 12                  | 15                | 18                  | 21                |
| Total Comparator Positive for PPA Calculation | 144              | 92                | 94                  | 97                | 100                 | 103               |
| Total Test Positives for PPA Calculation      | 86               | 80                | 80                  | 80                | 81                  | 81                |
| <b>PPA</b>                                    | <b>59.7</b>      | <b>87.0</b>       | <b>85.1</b>         | <b>82.5</b>       | <b>81.0</b>         | <b>78.6</b>       |
| 95% CI (XX% - XX%)                            | 51.5-67.4        | 78.6-92.4         | 76.5-90.9           | 73.7-88.8         | 72.2-87.5           | 69.8-85.5         |
| NPA (%)                                       | 99.1%            |                   |                     |                   |                     |                   |
| 95% CI (XX% - XX%)                            | 98.0%-99.6%      |                   |                     |                   |                     |                   |



SARS-CoV-2 Clinical Performance in Subjects on Days Post Symptoms Onset

| Days of COVID-19 Symptoms | Number of Subject samples tested | Investigational Positives | Comparator Positives | % Positive Rate (by Comparator) | PPA (95% CI)                  |
|---------------------------|----------------------------------|---------------------------|----------------------|---------------------------------|-------------------------------|
| Day 0                     | 19                               | 2                         | 5                    | 26.3%                           | <b>40.0%</b><br>(11.8%-76.9%) |
| Day 1                     | 130                              | 24                        | 38                   | 29.2%                           | <b>63.2%</b><br>(47.3%-76.6%) |
| Day 2                     | 239                              | 24                        | 46                   | 19.2%                           | <b>52.2%</b><br>(38.1%-65.9%) |
| Day 3                     | 195                              | 24                        | 33                   | 16.9%                           | <b>72.7%</b><br>(55.8%-84.9%) |
| Day 4                     | 120                              | 12                        | 22                   | 18.3%                           | <b>54.5%</b><br>(34.7%-73.1%) |
| <b>Total</b>              | <b>703</b>                       | <b>86</b>                 | <b>144</b>           | <b>20.5%</b>                    | <b>59.7%</b><br>(51.6%-67.4%) |

Note: The five false positive subjects were excluded from the Investigational Positives count for the purpose of this table (i.e., DPSO stratified PPA).

## INFLUENZA A PERFORMANCE

Investigational Test results for FLU A vs. FDA-cleared molecular test

| FLU A                     | Comparators Positives | Comparators Negatives | Sum        |
|---------------------------|-----------------------|-----------------------|------------|
| Investigational Positives | 67                    | 3                     | <b>70</b>  |
| Investigational Negatives | 5                     | 624                   | <b>629</b> |
| <b>Sum</b>                | <b>72</b>             | <b>627</b>            | <b>699</b> |

Positive Percent Agreement =  $(67/72) = 93.1\%$  (95% CI: 84.8%-97%)

Negative Percent Agreement =  $(624/627) = 99.5\%$  (95% CI: 98.6%-99.8%)

## INFLUENZA B PERFORMANCE

Investigational Test results for FLU B vs. FDA-cleared molecular test

| FLU B                     | Comparators Positives | Comparators Negatives | Sum        |
|---------------------------|-----------------------|-----------------------|------------|
| Investigational Positives | 41                    | 2                     | <b>43</b>  |
| Investigational Negatives | 5                     | 651                   | <b>656</b> |
| <b>Sum</b>                | <b>46</b>             | <b>653</b>            | <b>699</b> |

Positive Percent Agreement =  $(41/46) = 89.1\%$  (95% CI: 77%-95.3%)

Negative Percent Agreement =  $(651/653) = 99.7\%$  (95% CI: 98.9%-99.9%)

## SERIAL TESTING

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 SARS-CoV-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 tests 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 symptomatic individuals is described in the table below. 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.

*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 PCR POSITIVE TEST RESULT | SYMPTOMATIC ON FIRST DAY OF TESTING                            |                  |                   |
|-------------------------------------------|----------------------------------------------------------------|------------------|-------------------|
|                                           | AG POSITIVE / PCR POSITIVE<br>(ANTIGEN TEST PERFORMANCE % PPA) |                  |                   |
|                                           | 1 TEST                                                         | 2 TEST           | 3 TEST            |
| 0                                         | 34/57<br>(59.6%)                                               | 47/51<br>(92.2%) | 44/47<br>(93.6%)  |
| 2                                         | 58/62<br>(93.5%)                                               | 59/60<br>(98.3%) | 43/43<br>(100.0%) |
| 4                                         | 55/58<br>(94.8%)                                               | 53/54<br>(98.1%) | 39/40<br>(97.5%)  |
| 6                                         | 27/34<br>(79.4%)                                               | 26/33<br>(78.8%) | 22/27<br>(81.5%)  |
| 8                                         | 12/17<br>(70.6%)                                               | 12/17<br>(70.6%) | 7/11<br>(63.6%)   |
| 10                                        | 4/9<br>(44.4%)                                                 | 3/7<br>(42.9%)   |                   |

1 Test = one (1) test performance on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.

2 Tests = two (2) tests performance an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.

3 Tests = three (3) tests performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

## **ASSISTANCE**

If you have questions regarding the use of this product, or if you want to report a problem with the OSOM Flu SARS-CoV-2 Combo Test, please contact SEKISUI Diagnostics Technical Services at (800) 332-1042 or [techservices@sekisuidiagnostics.com](mailto:techservices@sekisuidiagnostics.com).

## **REFERENCES**

1. US Department of Health and Human Services. National Institutes of Health. Influenza [Fact Sheet]. January 2011.
2. Montalto N, Byrd R. An Office-Based Approach to Influenza: Clinical Diagnosis and Laboratory Testing. *American Family Physician*. January 2003; 67:11-118.
3. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. *Nat Rev Microbiol* 2019; 17: 181-192.
4. Lauer S, et al. The Incubation Period of Coronavirus Disease 2019 (COVID-19) From Publicly Reported Confirmed Cases: Estimation and Application. *Ann Intern Med* 2020 May 5;172(9):577-582.
5. CLSI. Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline – Fourth Edition. CLSI document M29-A4. Wayne, PA: Clinical and Laboratory Standards.

## **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



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



Consult instructions for use



Contains sufficient for <n> tests



Device for near-patient testing



Device not for self-testing



Do not re-use



In Vitro Diagnostic Medical Device



Quantity



Manufacturer



Negative control



Positive control



Temperature limit



Uncontaminated 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.



Use-by date



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SEKISUI Diagnostics, LLC  
6659 Top Gun Street  
San Diego, CA 92121 USA



**SEKISUI** Tel: 800-332-1042  
sekisuidiagnostics.com  
**DIAGNOSTICS**

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3523-4-df  
02/2024

# osom<sup>®</sup>

## Flu SARS-CoV-2 Combo Test

### QUICK REFERENCE GUIDE

REF 1080

IVD R<sub>ONLY</sub>

For use under an Emergency Use Authorization (EUA) only  
For *in vitro* diagnostic use  
For use with anterior nasal swab specimens.

Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results. Refer to the Instructions for Use (IFU) for more complete information.

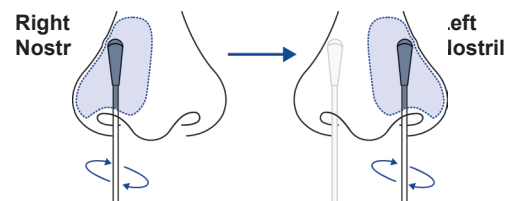
#### SAMPLE COLLECTION

1 GENTLY INSERT the swab no more than 3/4 of an inch into the nostril. For young children, swab should not be inserted more than 1/2 inch.

⚠ DO NOT insert the swab any farther if you feel any resistance.

2 SLOWLY ROTATE the swab at least 4 times against the nostril wall.

3 REMOVE the swab and repeat in the other nostril using the same swab.

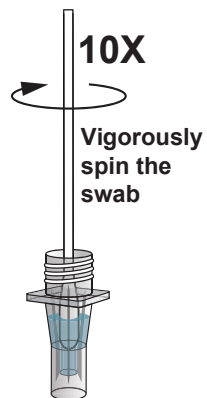


4 Sample must be mixed in the extraction buffer within 30 minutes of sample collection. Sample should be processed in the Extraction Buffer as soon as possible after collection.

#### RUNNING THE TEST

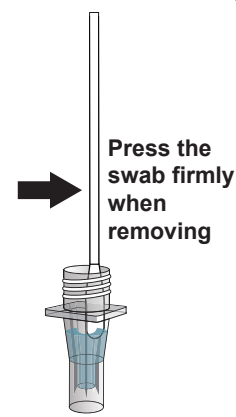
1 TWIST cap off Buffer vial. INSERT the swab through the ridges into the liquid. MIX thoroughly by spinning the swab at least 10 times in the liquid.

NOTE: Nasal swabs may not reach the bottom of the vial. Ensure that the swab is fully immersed in the liquid when mixing.



#### RUNNING THE TEST (CONTINUED)

2 PRESS the swab against the side of the vial to remove any excess sample in the swab. REMOVE and DISCARD the swab.



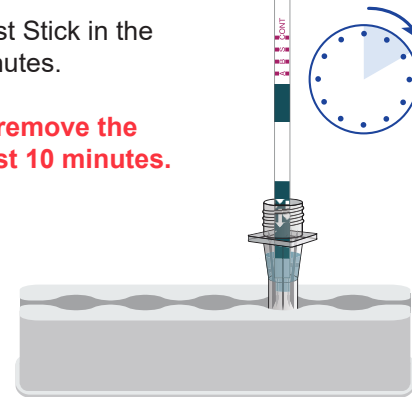
3 INSERT Test Stick (arrows pointing downward) into the vial. SET a timer for 10 minutes

NOTE: Leave the Test Stick in the vial for the full 10 minutes.

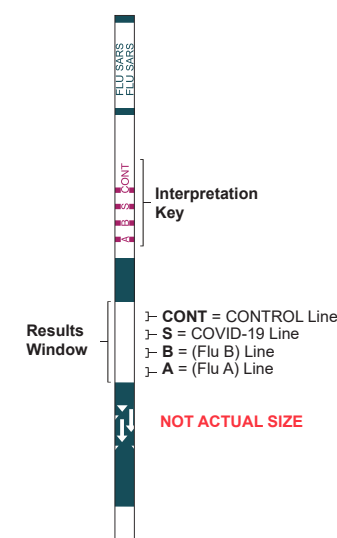
⚠ DO NOT handle or remove the Test Stick for at least 10 minutes.

4 READ test at 10 minutes. Do not read test before 10 minutes or after 30 minutes. See Interpretation of Results.

NOTE: You may need to remove the Test Stick to read the test results.



#### INTERPRETATION OF RESULTS

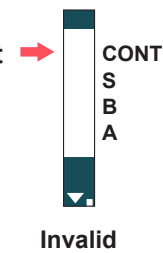


PLACE Test Stick, arrows pointing down, within dashed area of the Result Interpretation Card included in the kit. Ensure arrows on the Test Stick are pointing in the same direction as the arrows on the Result Interpretation Card and that the Results Window is aligned.

LOOK CLOSELY WHEN INTERPRETING THE RESULTS!

#### INVALID TEST RESULT

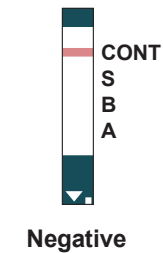
CHECK to see if a line is visible at the Control line "CONT". If a Control line is not visible at "CONT" after 10 minutes, even if any of the other lines are visible in the results window, THE TEST HAS FAILED and is considered invalid.



If the test is invalid, a new test should be performed with a new patient sample, Extraction Buffer vial, and Test Stick.

#### NEGATIVE TEST RESULT

If the Control line at "CONT" is visible and you do not see a line at "S", "B" or "A", it means COVID-19, Flu B, or Flu A virus have not been detected.

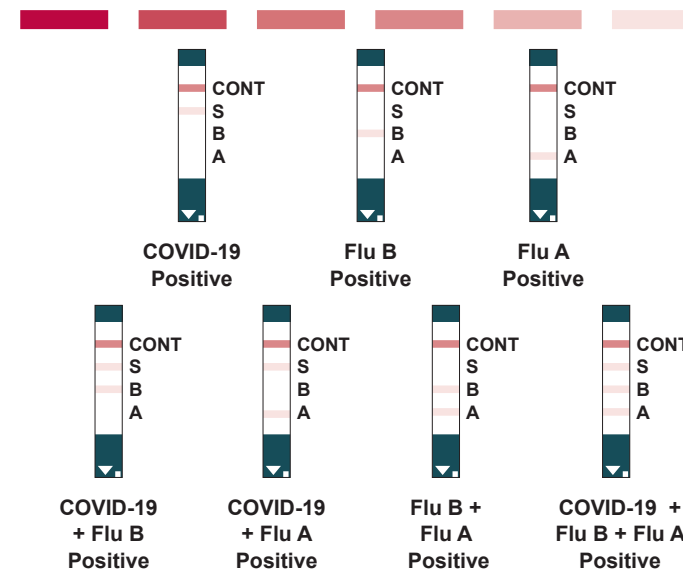


Negative results should be reported as a presumptive negative for the presence of influenza and/or SARS-CoV-2 antigen.

#### POSITIVE TEST RESULT

If the Control line at "CONT" is visible and any other line or multiple lines at "S", "B" and/or "A" appear, the test is positive.

NOTE: Any pink/red line, no matter how faint, should be considered an indication of a positive result.



It is possible to have more than one positive Test Line, which could indicate a co-infection with influenza A, B, and/or SARS-CoV-2, the virus that causes COVID-19. If more than one positive Test Line is observed, retest with a new patient sample, Extraction Buffer vial, and Test Stick. A differing result should be followed by confirmatory testing with another test method, such as PCR.

Laboratories within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities.

#### SERIAL TESTING

Repeat Testing is needed for all samples that are negative for SARS-CoV-2 on the first day of testing, even if they are positive for influenza A and/or B. Repeat testing is needed to improve test accuracy for SARS-CoV-2. Please follow the table below when interpreting test results. Serial (repeat) testing does not need to be performed if patients have a positive SARS-CoV-2 result on the first day of testing.

| Status on First Day of Testing: With Symptoms |                 |                                            |                                                                         |
|-----------------------------------------------|-----------------|--------------------------------------------|-------------------------------------------------------------------------|
| Day 0 (First Test)                            | Serial Testing? | Day 2 (Second Test)                        | Interpretation                                                          |
| SARS-CoV-2 (+)<br>Influenza A and B (-)       | NO              | Not needed                                 | Positive for COVID-19<br>Presumptive negative for Influenza             |
| SARS-CoV-2 (+)<br>Influenza A and/or B (+)    | NO              | Not needed                                 | Positive for COVID-19<br>Positive for Influenza A and/or B              |
| SARS-CoV-2 (-)<br>Influenza A and/or B (-)    | YES             | SARS-CoV-2 (+)<br>Influenza A and/or B (-) | Positive for COVID-19<br>Presumptive Negative for Influenza             |
| SARS-CoV-2 (-)<br>Influenza A and/or B (+)    | YES             | SARS-CoV-2 (+)<br>Influenza A and/or B (+) | Positive for COVID-19<br>Positive for Influenza A and/or B              |
| SARS-CoV-2 (-)<br>Influenza A and/or B (-)    | YES             | SARS-CoV-2 (-)<br>Influenza A and/or B (+) | Presumptive Negative for COVID-19<br>Positive for Influenza A and/or B  |
| SARS-CoV-2 (-)<br>Influenza A and/or B (-)    | YES             | SARS-CoV-2 (-)<br>Influenza A and/or B (-) | Presumptive Negative for COVID-19<br>Presumptive Negative for Influenza |
| SARS-CoV-2 (-)<br>Influenza A and/or B (+)    | YES             | SARS-CoV-2 (+)<br>Influenza A and/or B (+) | Positive for COVID-19<br>Positive for Influenza A and/or B              |
| SARS-CoV-2 (-)<br>Influenza A and/or B (-)    | YES             | SARS-CoV-2 (-)<br>Influenza A and/or B (-) | Presumptive Negative for COVID-19<br>Presumptive Negative for Influenza |
| SARS-CoV-2 (-)<br>Influenza A and/or B (+)    | YES             | SARS-CoV-2 (+)<br>Influenza A and/or B (+) | Positive for COVID-19<br>Positive for Influenza A and/or B              |
| SARS-CoV-2 (-)<br>Influenza A and/or B (+)    | YES             | SARS-CoV-2 (-)<br>Influenza A and/or B (+) | Presumptive Negative for COVID-19<br>Positive for Influenza A and/or B  |
| SARS-CoV-2 (-)<br>Influenza A and/or B (+)    | YES             | SARS-CoV-2 (+)<br>Influenza A and/or B (+) | Positive for COVID-19<br>Positive for Influenza A and/or B              |

#### EXTERNAL QUALITY CONTROL PROCEDURE

To perform a positive or negative control test, complete the steps in the Test Procedure section, treating the control swab in the same manner as a patient swab.

Minimally, SEKISUI Diagnostics recommends that positive and negative external controls be run with each new lot, shipment received, and with each new untrained operator.



## WARNINGS AND PRECAUTIONS

1. Do not use the kit contents beyond the expiration date printed on the outside of the box.
2. Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
3. The **Result Interpretation Card** should be cleaned after each use by spraying the laminated card with 70% ethanol alcohol or alternately by wiping with a clean towel moistened with 70% ethanol alcohol. The **Result Interpretation Card** should be wiped dry with a clean towel.
4. **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.**
5. This test may only be used in symptomatic individuals.

## EUA - WARNINGS AND PRECAUTIONS

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 and B, 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.

## INTENDED USE


**Please see the Instructions for Use for the full intended use.**

The OSOM® Flu SARS-CoV-2 Combo Test is a lateral flow immunochromatographic assay intended for in vitro rapid, simultaneous qualitative detection and differentiation of influenza A and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly from anterior nasal swab specimens of individuals with signs and symptoms of respiratory infection consistent with COVID-19 by their healthcare provider within the first four (4) days of symptom onset when tested at least twice over three days with at least 48 hours between tests. Results are for the simultaneous in vitro detection and differentiation of SARS-CoV-2, influenza A virus, and influenza B virus protein antigen, but does not differentiate, between SARS-CoV and SARS-CoV-2 viruses and is not intended to detect influenza C antigens. It is intended to aid in the rapid differential diagnosis of influenza A, influenza B, and COVID-19 viral infections.

## SUPPORT

If you have questions regarding the use of this product, or if you want to report a problem with the test, please contact SEKISUI Diagnostics Technical Services at (800) 332-1042 or [techservices@sekisuidiagnostics.com](mailto:techservices@sekisuidiagnostics.com).

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 SEKISUI Diagnostics, LLC  
6659 Top Gun Street  
San Diego, CA 92121 USA  
[sekisuidiagnostics.com](http://sekisuidiagnostics.com)

**SEKISUI**  
DIAGNOSTICS

3520-2-df  
02/2024

# 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  
6659 Top Gun Street  
San Diego, CA 92121 USA



**SEKISUI**  
**DIAGNOSTICS**

Tel: 800-332-1042  
[sekisuidiagnostics.com](http://sekisuidiagnostics.com)