OSOM®

COVID-19/Flu A&B Combo Test

For *In Vitro* Diagnostic Use
For Prescription Use Only
For Use with Kit Provided Swabs

INSTRUCTIONS FOR USE

IVD Rx ONLY REF 1099

CLIA Complexity-WAIVED for Use with Anterior Nasal Swab
Laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the test
Failure to follow the instructions or any modification to the manufacturer's instructions will result in the test being classified as high complexity

INTENDED USE

The OSOM® COVID-19/Flu A&B Combo Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly in anterior nasal swab (ANS) samples from individuals with signs and symptoms of respiratory tract infection. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

All negative results are presumptive and should be confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out infection with influenza or SARS-CoV-2 and should not be used as the sole basis for treatment or patient management decisions.

Positive results do not rule out bacterial infection or co-infection with other viruses.

SUMMARY AND EXPLANATION OF THE TEST

COVID-19 and influenza are acute highly contagious viral infections primarily affecting the respiratory tract caused by immunologically diverse, single-stranded RNA viruses known as SARS-CoV-2 and Influenza viruses respectively. There are three types of influenza viruses: A, B and C. Type A influenza is most prevalent and linked to severe illnesses, often causing epidemics. Type B causes milder illness and less frequent outbreaks, while Type C rarely causes widespread disease. COVID-19, caused by the novel coronavirus SARS-CoV-2, emerged in late 2019. Due to its rapid spread, the World Health Organization (WHO) declared a global pandemic on March 11, 2020.[1]

A patient can be infected with a single virus or co-infected with SARS-CoV-2 and one or more types of influenza viruses. These viral infections occur more frequently during the respiratory illness season, which in the United States encompasses the fall and winter months. Symptoms typically manifest 3 to 7 days post-infection. Transmission of these viruses occurs readily through the coughing and sneezing of aerosolized droplets from infected individuals, who may be either symptomatic or asymptomatic. For symptomatic patients, the primary symptoms include fever, fatigue, dry cough, and loss of taste and smell. Additionally, nasal congestion, runny nose, sore throat, myalgia, and diarrhea are commonly associated symptoms.

The OSOM COVID-19/Flu A&B Combo Test provides a simple, rapid method for the direct detection of the presence or absence of influenza A, influenza B, and/or SARS-CoV-2 antigens using ANS specimens. Its user-friendly format and rapid results allow for quick diagnosis and aid in treatment and hospitalization decisions.

PRINCIPLE

The OSOM COVID-19/Flu A&B Combo Test is designed to detect the extracted nucleoprotein antigen specific to influenza A, and influenza B and the extracted nucleocapsid antigen specific to SARS-CoV-2 in ANS specimens directly collected from patients exhibiting signs or symptoms of a respiratory infection.[2-6]

The test strip enclosed in a cassette housing is comprised of the following components: sample pad, reagent pad, biotin pad, reaction membrane, and absorbent pad. The reagent pad contains colloidal gold conjugated with monoclonal antibodies (mAb) specific for SARS-CoV-2, influenza A, and influenza B target proteins. The biotin pad contains biotin conjugated with mAb specific for SARS-CoV-2. The reaction membrane contains the secondary antibodies for the proteins of Flu A and Flu B, and streptavidin for the biotinylated SARS-CoV-2 antibody. The whole strip is fixed inside a plastic cassette.

When the specimens are extracted and added to the sample well of the test device, Flu A, Flu B nucleoproteins and/or SARS-CoV-2 nucleocapsid antigen is present in the specimen, a complex form between the anti-Flu A/Flu B/ SARS-CoV-2 conjugate and the viral antigen will be captured by the streptavidin or specific anti-Flu A/Flu B mAb coated on the test line region (C/A/B line). The absence of the test line (C/A/B line) suggests a negative result. To serve as a procedural control, a red line will always appear in the control line region (CON) indicating that proper volume of sample has been added and membrane wicking has occurred. Any result without this control line is invalid.

REAGENTS AND MATERIALS

Provided with the test kit:

27 - Test devices in sealed aluminum foil pouch with desiccant
27 - Empty reagent tubes
27 - Ampules containing extraction buffer (0.3 mL)
27 - Sample collection swabs
1 - Positive control swab
1 - Negative control swab
1 - Instructions for Use (IFU)
1 - Quick Reference Guide (QRG)
1 - Tube Holder (for optional use)

Required but not provided:

- Timer
- Any necessary personal protective equipment

STORAGE AND STABILITY

- The test kit should be stored at 36-86°F (2-30°C) in the original sealed pouch. Do not freeze.
- Bring all test components to room temperature at least 30 minutes prior to use.
- The test is stable until the expiration date printed on the outside of the box. Do not use after the expiration date.

WARNINGS AND PRECAUTIONS

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- ***Do not use for individuals who have had symptoms for more than 4 days or no symptoms at all.***
- Do not use if any of the test kit contents or packaging is damaged.
- Do not use any test component after the expiration date printed on the outer packaging.
- Do not interchange kit contents from different lots.
- Test components are single use. Do not re-use.
- Once opened, the test card should be used within 60 minutes.
- Ensure that testing and result interpretation are conducted in a well-lit space with sufficient lighting.
- Do not use the kit to evaluate patient specimens if either the positive control swab or negative control swab fails to give the expected results.

- Nitrile or latex gloves should be worn when performing this test.
- Dispose of used contents as biohazardous waste in accordance with federal, state, and local requirements.
- Handle all specimens as though they contain infectious agents.
- Do not use this test for individuals who recently received nasally administered influenza A or influenza B vaccine, as they may have false positive test results after vaccination.
- The Extraction Reagent contains potentially harmful chemicals (see table below). If the test solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, seek medical advice: visit https://www.poison.org/contact-us Or call 1-800-222-1222.

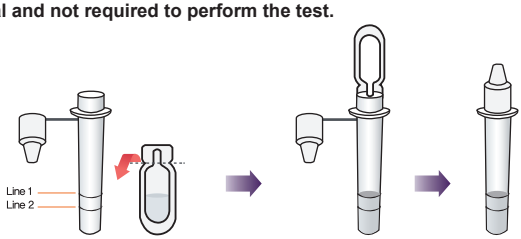
Chemical Name	Harms (GHS Code) for each ingredient	Concentration
Sodium Azide	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310	0.09%
Gentamicin	Skin Sens. 1, H317	0.004%

SAMPLE COLLECTION REAGENT PREPARATION

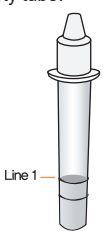
Fill the empty reagent tube with ampule solution.

NOTE: Do not open the test contents until ready for use. If the test cassette is open for an hour or longer, invalid test results may occur.

NOTE: A Tube Holder may be used to hold the reagent tube in an upright position during sample preparation for user convenience. Use of the Tube Holder is optional and not required to perform the test.



- Please look carefully, there are two lines on the empty tube.
- Flip over the TOP part of the ampule cap, then squeeze the ampule completely into the empty tube.



NOTE: The level of liquid must be above Line 1.

Do not proceed with this test, if the liquid level is below the Line 1, as this may result in false or invalid results.

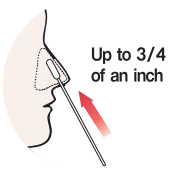
- Close the tube tightly with the dropper tip.

Collect Sample

The acceptable specimen type for testing with the OSOM COVID-19/Flu A&B Combo Test is a direct anterior nasal swab specimen. It is essential that correct specimen collection must be followed. Inadequate specimen collection, improper specimen handling and/or transport may yield false results; therefore, specimen collection requires specific training and guidance due to the importance of specimen quality to obtain accurate test results.

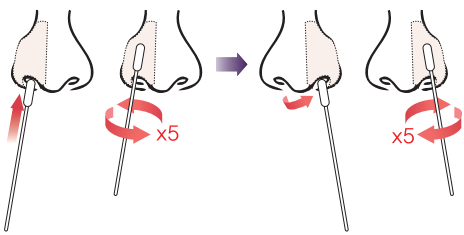
The freshly collected specimens should be processed as soon as possible, but no later than one hour after specimen collection when stored in a sterile container at room temperature (15-30°C) or within 24 hours when stored in a sterile container at 2-8°C. Do not freeze swab specimens before testing.

To collect the anterior nasal swab specimen, tilt the patient's head back 70 degrees and insert the soft end of the swab into patient's nostril no more than ¾ of an inch into the nose (no more than ½ inch if swabbing a child). Slowly rotate the swab, gently pressing against the inside of patient's nostril at least 5 times for a total of 15 seconds. Get as much nasal discharge as possible on the soft end of the swab. Gently remove the swab. Use the same end of the swab and repeat the same steps on the other nostril.



NOTE: When collecting a specimen, only use the swab provided in the kit.

NOTE: With children, the maximum depth of insertion into the nostril may be less than ¾ of an inch, and you may need to have a second person hold the child's head while swabbing.



NOTE: Failure to swab properly may cause false negative results.

NOTE: Be careful not to touch the swab tip (soft end) with hand.

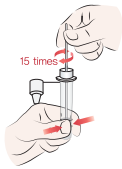
TEST PROCEDURE

Collect specimens according to instructions in "Specimen Collection". Test device and specimen should be brought to room temperature 59-86°F (15-30°C) prior to testing. Conduct all testing on a clean, level surface under ambient conditions. Carefully remove the test cassette from the sealed pouch and place it on the flat surface.

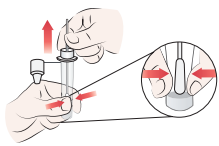
1 Tap the tube vertically on the table and remove the dropper tip to open the tube.



2 Insert the swab into the tube until the swab head touches the bottom of the tube. Hold the swab head at the bottom of the tube tightly by squeezing the tube. Then stir the swab at least 15 times.

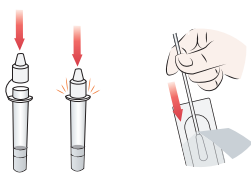


3 Squeeze the sides of the tube to express as much liquid as possible from the swab head and then remove the swab.

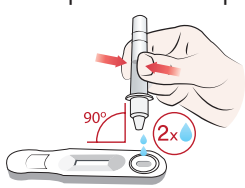


NOTE: If you don't squeeze the swab head, there may not be sufficient specimen material to perform the test properly (i.e., potentially resulting in a false negative result).

4 Firmly close the dropper tip, put the swab back into the package. Safely dispose of the swab and the package.



5 Hold the tube vertically to dispense the sample. Add 2 drops of sample to the Sample loading well of the Test device.



Caution: Invalid or false results can occur if less than 2 drops are added to the sample well.

NOTE: Specimen must be applied to the test cassette within 30 minutes of completing Step 2.

6 Wait 15 minutes after adding the sample to the Sample loading well and read the results at 15 minutes visually.



NOTE: False results can occur if the test is read before 15 minutes or after 20 minutes.

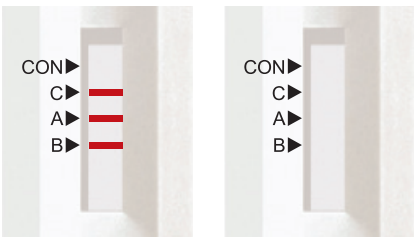
INTERPRETATION OF RESULTS



CON = Control line
C = COVID-19 line
A = Influenza A line
B = Influenza B line

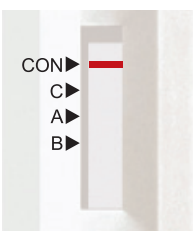
Look for lines next to CON, C, A, and B.

Invalid Result



A pinkish-red colored line should always appear at the Control line (CON) position. If a line does not form at the Control line position in 15 minutes, the test result is invalid and the test should be repeated with a new swab and a new test device. If the problem persists, please call SEKISUI Diagnostics Technical Services at +1-800-332-1042 or techservices@sekisuidiagnostics.com.

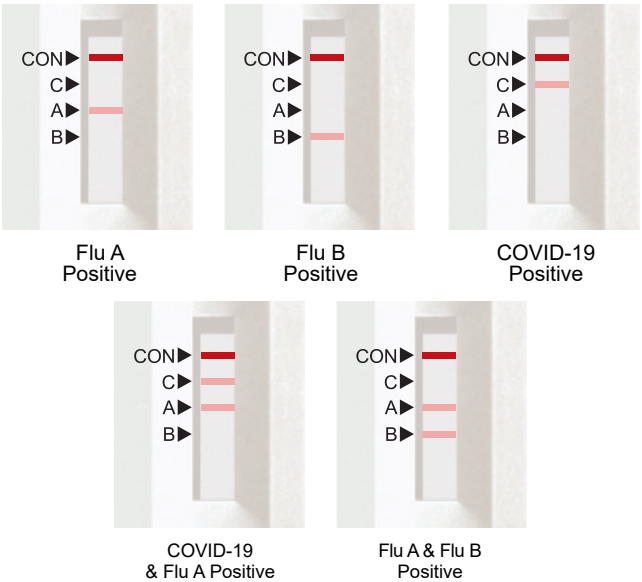
Negative Result



If the Control line (CON) is visible, but no other lines appear the test is negative.

NOTE: Negative results are presumptive and may be confirmed with a molecular assay, if necessary, for patient management.

Positive Result



If the Control line (CON) is visible and one or more lines appear(s) for any of the viruses, the test is positive for that or those viruses.

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 line of any intensity or thickness that appears in the Flu A (A), Flu B (B), or COVID-19 (C) 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 test line appear, 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 and new test kit. Repeatable "dual positive" results should be confirmed by an FDA-cleared molecular assay before reporting results.

QUALITY CONTROL

Internal Quality Control: The presence of a pinkish-red colored band in the Control area of the window acts as an internal control to ensure adequate migration has occurred but does not determine if an adequate sample has been added. In the absence of this Control line, the test is invalid and must be repeated. If the control line does not develop in 15 minutes, the test result is considered invalid, and retesting with a new device is recommended.

If the internal procedural Control line is still absent on the retest, please contact SEKISUI Diagnostics Technical Services at +1-800-332-1042 or techservices@sekisuidiagnostics.com.

External Control: Positive and negative control swabs are supplied with each kit. These controls provide additional quality control material to assess that the test kit reagents perform as expected. Process the controls in the same manner as the

clinical specimen swab, and conduct the assay as described in the Test Procedure section. Controls should minimally be run before using each new lot or shipment of OSOM COVID-19/Flu A&B Combo Test, before testing is conducted by each new operator, at regular intervals afterward or any time when the validity of the test results is questioned. All users should follow local, state, and federal regulations regarding quality control procedures.

If the controls do not perform as expected, do not report patient results. Please contact SEKISUI Diagnostics Technical Services at +1-800-332-1042 or techservices@sekisuidiagnostics.com.

LIMITATIONS

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between November 2022 and February 2025. There is a risk of false negative results due to the presence of novel, emerging respiratory virus variants. Test accuracy may change as new virus variants of COVID-19 and influenza emerge. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of COVID-19 and influenza and their prevalence, which change over time. Additional testing with a laboratory-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.
- 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 influenza and SARS-CoV-2 as compared to a molecular test, especially in samples with low viral load.
- This test provides a presumptive negative result; this means the test only provides preliminary results that should be confirmed using an independent, highly sensitive molecular test to make well-informed clinical decisions.
- Use of OSOM COVID-19/Flu A&B Combo Test is limited to laboratory personnel and CLIA-waived users. Not for home use.
- Viral transport media (VTM) should not be used with this test.
- The contents of this kit are to be used as a qualitative test and do not provide information on the viral concentration present in the specimen.
- The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection.
- This test detects both viable (live) and non-viable influenza A, influenza B, and SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the specimen and may or may not correlate with viral culture results performed on the specimen.
- A negative test result may occur if the level of antigen in the sample is below the detection limit of the test or if the specimen is collected, handled or transported improperly.
- Positive results do not rule out co-infection with other respiratory pathogens.
- Positive test results do not identify specific coronavirus, influenza A and B subtypes and strains. If differentiation of specific coronavirus or influenza A, influenza B subtypes and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely during peak activity when the prevalence of the disease is high. False positive test results are more likely during periods of low viral activity when prevalence is moderate to low.
- This test was not evaluated for use with the FluMist® vaccine. Individuals who recently received nasally administered influenza A or influenza B vaccine may have false positive test results after vaccination.

EXPECTED VALUE

The rate of positivity as determined by the OSOM COVID-19/Flu A&B Combo Test during the 2022-2025 clinical study was 21.5% for influenza A (423/1,969), 5.3% for influenza B (104/1,969), and 11.9% for SARS-CoV-2 (235/1,969).

CLINICAL PERFORMANCE

The clinical performance of the OSOM COVID-19/Flu A&B Combo Test was established with 1,969 anterior nasal samples that were prospectively collected from subjects between November 2022 and February 2025 at six clinical CLIA waived sites in the U.S. Samples were collected from sequentially enrolled subjects who presented with symptoms of respiratory infection. Two anterior nasal swabs were collected from each study subject during the same visit with the comparator collected first, followed by collection of the candidate test sample. Samples were tested with the OSOM COVID-19/Flu A&B Combo Test. All subjects were confirmed as positive or negative by an FDA-cleared RT-PCR method, used as the comparator method for the study. OSOM COVID-19/Flu A&B Combo Test was performed by operators who had no prior experience in the laboratory and were representative of the intended users in CLIA-waived settings. Operators used only the QRI to conduct testing without training provided. All testing was conducted by operators in a blinded fashion.

For SARS-CoV-2 detection, out of the 265 samples that tested positive with the comparator RT-PCR test, 232 were positive and 33 were negative using OSOM COVID-19/Flu A&B Combo Test. Additionally, 1,701 out of 1,704 samples that were negative on RT-PCR were also negative on OSOM COVID-19/Flu A&B Combo Test. The agreement between the OSOM COVID-19/Flu A&B Combo Test and RT-PCR are presented below.

Table 1.1: OSOM COVID-19/Flu A&B Combo Test-Results for SARS-CoV-2

OSOM COVID-19/Flu A&B Combo Test	Comparator RT-PCR		Total
	Positive	Negative	
Positive	232	3	235
Negative	33	1,701	1,734
Total	265	1,704	1,969

Positive Percent Agreement = (232/265) = 87.6% (95% CI: 83.0%-91.0%)

Negative Percent Agreement = (1,701/1,704) = 99.8% (95% CI: 99.5%-99.9%)

Table 1.2: SARS-CoV-2 Results by Age Group versus Comparator RT-PCR

Age Group	Comparator RT-PCR		
	# of Specimens Tested	# of Positive Specimens	Prevalence (%)
≤5 years	416	27	6.5
6 to 21 years	863	75	8.7
22 to 60 years	517	117	22.6
≥61 years	173	46	26.6
Total	1,969	265*	13.5

** OSOM COVID-19/Flu A&B Combo Test yielded positive results for 23 samples (85.2%) in the age group below 5 years old, 66 samples (88.0%) in the age group of 6 to 21 years, 99 samples (84.6%) in the age group of 22 to 60 years, and 44 samples (95.7%) in the age group more than 61 years.*

Table 1.3: SARS-CoV-2 Positive Results Stratified by Days Post-Symptom Onset

Days Post Onset	RT-PCR Positive	OSOM COVID-19/ Flu A&B Combo Test Positive	Positive Rate (%)	95% CI
1	82	74	90.2	81.9-95.0

Table 1.3: SARS-CoV-2 Positive Results Stratified by Days Post-Symptom Onset

Days Post Onset	RT-PCR Positive	OSOM COVID-19/ Flu A&B Combo Test Positive	Positive Rate (%)	95% CI
2	98	85	86.7	78.6-92.1
3	64	56	87.5	77.2-93.5
4	21	17	81.0	60.0-92.3
Total	265	232	87.6	83.0-91.0

For influenza A detection, out of the 480 samples that tested positive with the comparator RT-PCR test, 417 were positive and 63 were negative using Nano-Check™ Influenza+COVID-19 Dual Test. Additionally, 1,483 out of 1,489 samples that were negative on RT-PCR were also negative on Nano-Check™ Influenza+COVID-19 Dual Test. The agreement between the OSOM COVID-19/Flu A&B Combo Test and RT-PCR are presented below.

Table 1.4: OSOM COVID-19/Flu A&B Combo Test-Results for Influenza A

OSOM COVID-19/Flu A&B Combo Test	Comparator RT-PCR		Total
	Positive	Negative	
Positive	417	6	423
Negative	63	1,483	1,546
Total	480	1,489	1,969

Positive Percent Agreement = (417/480) = 86.9% (95% CI: 83.6%-89.6%)

Negative Percent Agreement = (1,483/1,489) = 99.6% (95% CI: 99.1%-99.8%)

For influenza B detection, out of the 114 samples that tested positive with the comparator RT-PCR test, 99 were positive and 15 were negative using Nano-Check™ Influenza+COVID-19 Dual Test. Additionally, 1,850 out of 1,855 samples that were negative on RT-PCR were also negative on Nano-Check™ Influenza+COVID-19 Dual Test. The agreement between the OSOM COVID-19/Flu A&B Combo Test and RT-PCR are presented below.

Table 1.5: OSOM COVID-19/Flu A&B Combo Test-Results for Influenza B

OSOM COVID-19/Flu A&B Combo Test	Comparator RT-PCR		Total
	Positive	Negative	
Positive	99	5	104
Negative	15	1,850	1,865
Total	114	1,855	1,969

Positive Percent Agreement = (99/114) = 86.8% (95% CI: 79.4%-91.9%)

Negative Percent Agreement = (1,850/1,855) = 99.7% (95% CI: 99.4%-99.9%)

ASSAY SENSITIVITY: LIMIT OF DETECTION (LOD)

The limit of detection (LoD) for OSOM COVID-19/Flu A&B Combo Test was established using serial dilutions of two SARS-CoV-2 Omicron variant strains (USA/MD-HP20874/2021, USA/COR-22-0631 13/2022), two influenza A strains (Influenza A H1N1: A/California/04 /2009, Influenza A H3N2: A/Victoria/361/2011) and two influenza B strains (Influenza B/Hong Kong/330/2001 and Influenza B/Phuket/3073 /13) in a negative clinical matrix. Contrived samples were prepared by spiking the isolate/strain into the pooled negative nasal fluid solution confirmed negative for SARS-CoV-2, influenza A, and influenza B by RT-PCR. A preliminary LoD was determined by spiking 50 µL of serially diluted sample onto swab heads and tested using the Nano-Check™ Influenza+COVID-19 Dual Test. A preliminary LoD test was performed by spiking 50 µL of each diluted sample onto the sample collection swab head. The confirmatory LoD test was performed at the selected preliminary LoD concentration and at concentrations above and below the preliminary LoD with an additional 20 replicates. Based on the testing procedure for this study, the results of LoD are presented in the table below.

Table 2.1: LoD Confirmation for SARS-CoV-2, Influenza A, and Influenza B

Virus Strain	LoD	% Positive
SARS-CoV-2: USA/MD-HP20874/2021, Heat Inactivated	1.95×10^2 $TCID_{50}$/mL (9.75×10^0 $TCID_{50}$/swab)	95%
SARS-CoV-2: USA/COR-22-063113/2022, Heat Inactivated	1.27×10^4 $TCID_{50}$/mL (6.35×10^2 $TCID_{50}$/swab)	100%
Influenza A H1N1: A/California/04/2009	2.8×10^3 $TCID_{50}$/mL (1.4×10^2 $TCID_{50}$/swab)	100%
Influenza A H3N2: Victoria/361/2011	1.4×10^5 $CEID_{50}$/mL (7.0×10^3 $CEID_{50}$/swab)	95%
Influenza B Victoria: B/Hong Kong/330/2001	2.25×10^5 $CEID_{50}$/mL (1.13×10^4 $CEID_{50}$/swab)	95%
Influenza B Yamagata: B/Phuket/3073/13	1.04×10^2 $TCID_{50}$/mL (5.2×10^0 $TCID_{50}$/swab)	100%

Furthermore, the LoD studies with the 1st WHO International Standard for SARS-CoV-2 Antigen (NIBSC 21/368) were determined and the results are presented below.

Table 2.2: LoD Confirmation for SARS-CoV-2, Influenza A, and Influenza B

Description	Source	NIBSC. No.	Concentration (IU/mL)	IU/Swab	% Positive
WHO Standard	NIBSC	21/368	667	33.5	95

ANALYTICAL REACTIVITY/INCLUSIVITY

The analytical inclusivity (sensitivity) was established for a total of 14 strains of SARS-CoV-2, 31 strains of influenza A, and 16 strains of influenza B, including most representing subtypes from past to recent.

Table 3: Summary of Analytical Reactivity (Inclusivity)

Virus	Virus Strains	Concentration	Units
SARS-CoV-2 (B.1.1.7, Alpha)	USA/CA/CDC/5574/2020[1])	6.77E+06	GE /mL
	USA/CA/CDC/5574/2020[2])	2.39E+04	$TCID_{50}$/mL
	England/204820464/2020	7.19E+03	$TCID_{50}$/mL
SARS-CoV-2 (B.1.351, Beta)	USA/MD-HP01542/2021[3])	7.20E+04	GC/mL
	USA/MD-HP01542/2021[4])	3.80E+06	GC/mL
	South Africa/KRISP-K0053 25/2020	1.90E+04	$TCID_{50}$/mL
SARS-CoV-2 (B.1.617.2, Delta)	USA/MD-HP05285/2021[5])	7.20E+07	GC/mL
	USA/MD-HP05285/2021[6])	5.00E+06	GC/mL
	USA/PHC658/2021	5.21E+02	$TCID_{50}$/mL
SARS-CoV-2 (P.1, Gamma	Japan/TY7-503/2021	1.58E+04	$TCID_{50}$/mL
	USA/NY-Wadsworth-21033 899-01/ 2021	7.85E+03	$TCID_{50}$/mL
SARS-CoV-2 (B.1.617.1, Kappa)	USA/CA-Stanford-15_S02/ 2021	8.48E+04	$TCID_{50}$/mL
SARS-CoV-2 (B.1.1.529, Omicron)	USA/GA-EHC-2811C/2021	2.11E+07	GC/mL
SARS-CoV-2 (B.1.1.529, Omicron)	USA/New York/PV96109/20 23	3.14E+03	$TCID_{50}$/mL

1) Source: Bei Resources (Cat. #: NR-55245, Lot#:70043111), 2) Source: ZeptoMetrix (Cat. #: 0810612CFHI, Lot#:328055), 3) Source: Bei Resources (Cat. #: NR-553651, Lot#:70045299), 4) Source: Bei Resources (Cat. #: NR-55350, Lot#:70045608), 5) Source: Bei Resources (Cat. #: NR-56128, Lot#:70048021), 6) Source: ATCC (Cat. #: VR-3342HK, Lot#:70048932)

Table 3: Summary of Analytical Reactivity (Inclusivity)

Virus	Virus Strains	Concentration	Units
Flu A H1N1	A/Puerto Rico/8/34	8.00E+06	$CEID_{50}$/mL
	A/Brisbane/59/2007	4.45E+06	$CEID_{50}$/mL
	A/Denver/1/57	4.00E+05	$CEID_{50}$/mL
	A/San Diego/1/2009 pdm09	2.80E+04	$TCID_{50}$/mL
	A/Tijuana/4/09	2.45E+01	$TCID_{50}$/mL
	A/Solomon Islands/3/2006	4.45E+05	$CEID_{50}$/mL
	A/NWS/33	1.23E+05	$CEID_{50}$/mL
	A/FM/1/47	4.25E+05	$CEID_{50}$/mL
	A/New Jersey/8/76	1.70E+04	$CEID_{50}$/mL
	A/New Caledonia/20/1999	4.00E+05	$CEID_{50}$/mL
	A/Hawaii/66/2019	1.28	HA
	A/Hawaii/66/2019 X-345A	1.28	HA
	A/Guangdong-Maonan/1536/ 2019	1.28	HA
	A/Guangdong-Maonan/1536/ 2019 CNIC-1909	0.64	HA
	A/Victoria/4897/2022(pdm09)	1.58E+07	EID50/mL
	A/Victoria/2570/2019(pdm09)	9.98E+05	EID50/mL
Flu A H1N2	A/Swine/Ohio/09SW1477/2009	2.30E+04	$TCID_{50}$/mL
Flu A H3N2	A/Hong Kong/8/1968	1.40E+05	$CEID_{50}$/mL
	A/Aichi/2/1968	4.00E+05	$CEID_{50}$/mL
	A/Wisconsin/67/2005	7.00E+05	$CEID_{50}$/mL
	A/Hong Kong/4801/2014	9.60E+05	$CEID_{50}$/mL
	A/Netherlands/22/2003	8.00E+02	$TCID_{50}$/mL
	A/Netherlands/823/1992	1.44E+01	$TCID_{50}$/mL
	A/Brisbane/10/2007	1.38E+05	$CEID_{50}$/mL
	A/Wisconsin/15/2009	5.00E+03	$CEID_{50}$/mL
	A/Sydney/5/97	4.45E+04	$CEID_{50}$/mL
	A/Port Chalmers/1/73	2.00E+05	$CEID_{50}$/mL
	A/Victoria/3/75	4.00E+05	$CEID_{50}$/mL
	A/Perth/16/2009 x A/Puerto Rico/8/19 34, NIB-64	2.80E+06	$CEID_{50}$/mL
	A/Singapore/INFIMH-16-0019 /16	2.51E+03	$TCID_{50}$/mL
Flu A H5N1	A/mallard/Wisconsin/2576/2009	5.25E+05	GE/mL

1) Source: Bei Resources (Cat. #: NR-55245, Lot#:70043111), 2) Source: ZeptoMetrix (Cat. #: 0810612CFHI, Lot#:328055), 3) Source: Bei Resources (Cat. #: NR-553651, Lot#:70045299), 4) Source: Bei Resources (Cat. #: NR-55350, Lot#:70045608), 5) Source: Bei Resources (Cat. #: NR-56128, Lot#:70048021), 6) Source: ATCC (Cat. #: VR-3342HK, Lot#:70048932)

Table 3: Summary of Analytical Reactivity (Inclusivity)

Virus	Virus Strains	Concentration	Units
Flu B (Victoria Lineage)	B/Brisbane/60/2008	9.00E+04	$CEID_{50}$/mL
	B/Malaysia/2506/2004	1.12E+06	$CEID_{50}$/mL
	B/New York/1056/2003	3.20E+03	$TCID_{50}$/mL
	B/Washington/02/2019	1.28	HA
Flu B (Yamagata Lineage)	B/Florida/78/2015	2.80E+04	$TCID_{50}$/mL
	B/Texas/06/2011	4.45E+08	$CEID_{50}$/mL
	B/New York/1061/2004	8.00E+02	$TCID_{50}$/mL
	B/Christchurch/33/2004	8.00E+02	$TCID_{50}$/mL
	B/Sydney/507/2006	1.60E+05	$TCID_{50}$/mL
	B/Wisconsin/1/2010	1.80E+06	$CEID_{50}$/mL
	B/Florida/4/2006	3.50E+05	$CEID_{50}$/mL
Flu B (Non-Victoria/ Yamagata)	B/Colorado/6/17	1.78E+02	$TCID_{50}$/mL
	B/Taiwan/2/1962	4.45E+03	$CEID_{50}$/mL
	B/Lee/1940	9.00E+04	$CEID_{50}$/mL
	B/GL/1739/54	5.00E+04	$CEID_{50}$/mL
	B/Great Lakes/1739/1954	3.20E+04	$CEID_{50}$/mL

1) Source: Bei Resources (Cat. #: NR-55245, Lot#:70043111), 2) Source: ZeptoMetrix (Cat. #: 0810612CFHI, Lot#:328055), 3) Source: Bei Resources (Cat. #: NR-553651, Lot#:70045299), 4) Source: Bei Resources (Cat. #: NR-55350, Lot#:70045608), 5) Source: Bei Resources (Cat. #: NR-56128, Lot#:70048021), 6) Source: ATCC (Cat. #: VR-3342HK, Lot#:70048932)

ASSAY CROSS-REACTIVITY AND MICROBIAL INTERFERENCE

Cross-reactivity of the OSOM COVID-19/Flu A&B Combo Test was evaluated by testing 50 potential pathogens, including bacteria (19), fungi (1), viruses (28), and negative matrix (2) that could potentially cross-react with the OSOM COVID-19/Flu A&B Combo Test. The final concentration of each organism is described in the table below. The microbial interference was also performed with the same panel of microorganisms at the same concentrations in the samples that were spiked with SARS-CoV-2, influenza A, and influenza B viruses at 2 x LoD. The samples were tested in triplicate for both cross-reactivity and interference studies. No cross-reactivity and no microbial interference were observed. The results for cross-reactivity and microbial interference are presented in the table below.

Table 4: Summary of Cross-reactivity and Microbial Interference

Pathogen	Concentration Tested	Cross-Reactivity/ Microbial Interference
Bordetella pertussis	1.0×10^6 CFU/mL	No
Candida albicans	1.0×10^6 CFU/mL	No
Chlamydophila pneumoniae	1.0×10^6 IFU/mL	No
Corynebacterium diphtheriae	1.0×10^6 CFU/mL	No
Escherichia coli	1.0×10^6 IFU/mL	No

Coronavirus HKU1 was not tested for cross-reactivity due to a lack of availability. 20 clinical samples containing Coronavirus HKU1 were tested and all resulted as negative, however, the viral load/concentration of each sample is unknown.

Table 4: Summary of Cross-reactivity and Microbial Interference

Pathogen	Concentration Tested	Cross-Reactivity/ Microbial Interference
Haemophilus influenzae, B	1.0×10^6 CFU/mL	No
Lactobacillus acidophilus	1.0×10^6 CFU/mL	No
Legionella Pneumophila subsp. Pneumophila	1.0×10^6 CFU/mL	No
Moraxella catarrhalis	1.0×10^6 CFU/mL	No
Mycobacterium tuberculosis	1.0×10^6 CFU/mL	No
Mycoplasma pneumoniae	1.0×10^6 CFU/mL	No
Neisseria meningitidis	1.0×10^6 CFU/mL	No
Neisseria mucosa	1.0×10^6 CFU/mL	No
Neisseria subflava	1.0×10^6 CFU/mL	No
Pseudomonas aeruginosa	1.0×10^6 CFU/mL	No
Staphylococcus aureus	1.0×10^6 CFU/mL	No
Staphylococcus epidermidis	1.0×10^6 CFU/mL	No
Streptococcus pneumoniae	1.0×10^6 CFU/mL	No
Streptococcus pyogenes	1.0×10^6 CFU/mL	No
Streptococcus salivarius	1.0×10^6 CFU/mL	No
Epstein-Barr Virus	1.0×10^5 cp/mL	No
Enterovirus 71	1.0×10^5 $TCID_{50}$/mL	No
Enterovirus D 68	1.0×10^5 $TCID_{50}$/mL	No
Human Herpesvirus	8.0×10^4 $TCID_{50}$/mL	No
Human Adenovirus 1	1.0×10^5 $TCID_{50}$/mL	No
Human Adenovirus 2	1.0×10^5 $TCID_{50}$/mL	No
Human Adenovirus 7, Gomen	1.0×10^5 $TCID_{50}$/mL	No
Human Coronavirus, 229E	1.0×10^5 $TCID_{50}$/mL	No
Human Coronavirus, NL63	7.0×10^4 $TCID_{50}$/mL	No
Human Coronavirus, OC43	4.5×10^4 $TCID_{50}$/mL	No
Human Metapneumovirus 3, B1, Peru2-2002	1.95×10^4 $TCID_{50}$/mL	No
Human Metapneumovirus, TN/83-1211	1.0×10^5 $TCID_{50}$/mL	No
Human Parainfluenza Virus 1	1.0×10^5 $TCID_{50}$/mL	No
Human Parainfluenza Virus 2	1.0×10^5 $TCID_{50}$/mL	No
Human Parainfluenza Virus 3	1.0×10^5 $TCID_{50}$/mL	No
Human Parainfluenza Virus 4B	1.0×10^5 $TCID_{50}$/mL	No
Human RSV, A Long	1.0×10^5 $TCID_{50}$/mL	No
Human RSV, A 9320	1.0×10^5 $TCID_{50}$/mL	No
Human RSV, A2	1.0×10^5 $TCID_{50}$/mL	No
Human RSV, B 18537	1.0×10^5 $TCID_{50}$/mL	No

Coronavirus HKU1 was not tested for cross-reactivity due to a lack of availability. 20 clinical samples containing Coronavirus HKU1 were tested and all resulted as negative, however, the viral load/concentration of each sample is unknown.

Table 4: Summary of Cross-reactivity and Microbial Interference

Pathogen	Concentration Tested	Cross-Reactivity/ Microbial Interference
Human RSV, B WV/14617/85	1.0×10^5 $TCID_{50}$/mL	No
Human RSV, B1	1.0×10^5 $TCID_{50}$/mL	No
Human Rhinovirus 1A, 2060	1.0×10^5 PFU/mL	No
Measles Virus, Edmonston	1.7×10^4 $TCID_{50}$/mL	No
MERS-CoV, EMC/2012	1.0×10^5 $TCID_{50}$/mL	No
Mumps Virus, MuV/Iowa.US/2006	1.0×10^5 $TCID_{50}$/mL	No
Rhinovirus 20, 15-CV19	1.0×10^5 $TCID_{50}$/mL	No
SARS-CoV	1.0×10^5 PFU/mL	No
Pooled Human Nasal Wash	N/A	No
Pooled Human Nasal Fluid	N/A	No

Coronavirus HKU1 was not tested for cross-reactivity due to a lack of availability. 20 clinical samples containing Coronavirus HKU1 were tested and all resulted as negative, however, the viral load/concentration of each sample is unknown.

ENDOGENOUS/EXOGENOUS INTERFERENCE

To assess endogenous/exogenous interference with the performance of OSOM COVID-19/Flu A&B Combo Test, positive and negative samples were tested with potentially interfering substances that may be found in the upper respiratory tract. This study was performed to demonstrate that thirty-six (36) potentially interfering substances do not interfere with the detection of SARS-CoV-2, influenza A, or influenza B in OSOM COVID-19/Flu A&B Combo Test.

Table 5: Summary of Endogenous/Exogenous Interfering Substances

Interfering Substances	Concentration Tested	Interference (Yes/No)
Nasal Spray 1	15% v/v	No
Nasal Spray 2	15% v/v	No
Nasal Spray 3	15% v/v	No
Nasal Spray 4	15% v/v	No
Budesonide Nasal Spray	15% v/v	No
Nasonex 24 hr Allergy	15% v/v	No
Nasacort Allergy 24HR	15% v/v	No
Sore Throat (Oral Pain Reliever spay)	15% v/v	No
ZICAM® Oral mist	15% v/v	No
Sore Throat Lozenges	15% w/v	No
Zinc Cold Therapy	15% w/v	No
Homeopathic Allergy Nasal Spray	15% v/v	No
NasoGEL (Gel Spray)	15% v/v	No
Nasalcrom® Nasal Allergy spray	15% v/v	No
Histaminum 30C	15% w/v	No
Skin relief hand cream	1% w/v	No

**Hand sanitizer lotion tested at 15% w/v concentration resulted in false negative Influenza B results.*

Table 5: Summary of Endogenous/Exogenous Interfering Substances

Interfering Substances	Concentration Tested	Interference (Yes/No)
Hand Soap Fresh Breeze Scent	1% w/v	No
Antibacterial liquid Hand Soap	15% w/v	No
Hand sanitizer gel	15% w/v	No
Hand sanitizer lotion*	10% w/v	No
Disinfectant Spray	1% v/v	No
Acetylsalicylic acid	3.00×10^{1} µg/mL	No
Dexamethasone	1.20×10^{1} µg/mL	No
Mometasone furoate	4.50×10^{-4} µg/mL	No
Mupirocin	1.50×10^{0} µg/mL	No
Oseltamivir phosphate	3.99×10^{-1} µg/mL	No
Tobramycin	3.30×10^{1} µg/mL	No
Beclomethasone dipropionate	5.04 µg/mL	No
Flunisolide	870 µg/mL	No
Molnupiravir	3.29 mg/mL	No
Remdesivir	240 µg/mL	No
Zanamivir	30 mg/mL	No
Human Neutrophils	5×10^{6} cells/mL	No
Mucin -Bovine submaxillary Glands (Type I-S)	5 mg/mL	No
Whole Blood	2.50%	No
Biotin	3500 ng/mL	No

**Hand sanitizer lotion tested at 15% w/v concentration resulted in false negative Influenza B results.*

HIGH-DOSE HOOK EFFECT

No high-dose hook effect was observed with OSOM COVID-19/Flu A&B Combo Test when testing high concentrations of SARS-CoV-2, influenza A, or influenza B strains.

Table 6: Summary of High-dose Hook Effect

Virus Strain Tested	Concentration
SARS-CoV-2, USA/MD-HP20874/2021	3.89×10^{4} $TCID_{50}$/mL
SARS-CoV-2, USA/COR-22-063113/2022	2.53×10^{6} $TCID_{50}$/mL
Influenza A/California/04/2009	2.80×10^{6} $TCID_{50}$/mL
Influenza A/Victoria/361/2011	2.80×10^{8} $CEID_{50}$/mL
Influenza B/Hong Kong/330/2001	1.80×10^{7} $TCID_{50}$/mL
Influenza B/Phuket/3073/13	4.17×10^{5} $TCID_{50}$/mL

COMPETITIVE INHIBITION

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 OSOM COVID-19/Flu A&B Combo 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 tested in the presence of high concentrations of the other influenza virus. No competitive interference was observed between SARS-CoV-2 and influenza A and B as listed in the table below.

Table 7: Summary of Competitive Interference Results

High Titer Target		Low Titer Target		Low Titer Target Percent Positivity
Virus Name	**Concentration**	**Virus Name**	**Concentration**	
Flu A (H1N1)	2.8×10^5	SARS-CoV-2	3.81×10^4	100%
Flu A (H1N1)	2.8×10^5	Flu B (Victoria)	6.75×10^5	100%
Flu A (H1N1)	2.8×10^5	Flu B (Yamagata)	3.12×10^2	100%
Flu A (H3N2)	2.8×10^6	SARS-CoV-2	3.81×10^4	100%
Flu A (H3N2)	2.8×10^6	Flu B (Victoria)	6.75×10^5	100%
Flu A (H3N2)	2.8×10^6	Flu B (Yamagata)	3.12×10^2	100%
Flu B (Victoria)	1.8×10^6	SARS-CoV-2	3.81×10^4	100%
Flu B (Victoria)	1.8×10^6	Flu A (H1N1)	8.4×10^3	100%
Flu B (Victoria)	1.8×10^6	Flu A (H3N2)	4.2×10^5	100%
Flu B (Yamagata)	4.17×10^5	SARS-CoV-2	3.81×10^4	100%
Flu B (Yamagata)	4.17×10^5	Flu A (H1N1)	8.4×10^3	100%
Flu B (Yamagata)	4.17×10^5	Flu A (H3N2)	4.2×10^5	100%
SARS-CoV-2	2.53×10^5	Flu A (H1N1)	8.4×10^3	100%
SARS-CoV-2	2.53×10^5	Flu A (H3N2)	4.2×10^5	100%
SARS-CoV-2	2.53×10^5	Flu B (Victoria)	6.75×10^5	100%
SARS-CoV-2	2.53×10^5	Flu B (Yamagata)	3.12×10^2	100%
Flu A (H1N1)	2.8×10^5	Flu B (Yamagata)	3.12×10^2	100%
		SARS-CoV-2	3.81×10^4	100%
Flu A (H1N1)	2.8×10^5	Flu B (Victoria)	6.75×10^5	100%
		SARS-CoV-2	3.81×10^4	100%
Flu A (H3N2)	2.8×10^6	Flu B (Yamagata)	3.12×10^2	100%
		SARS-CoV-2	3.81×10^4	100%
Flu A (H3N2)	2.8×10^6	Flu B (Victoria)	6.75×10^5	100%
		SARS-CoV-2	3.81×10^4	100%
Flu B (Victoria)	1.8×10^6	Flu A (H1N1)	8.4×10^3	100%
		SARS-CoV-2	3.81×10^4	100%
Flu B (Victoria)	1.8×10^6	Flu A (H3N2)	4.2×10^5	100%
		SARS-CoV-2	3.81×10^4	100%

Table 7: Summary of Competitive Interference Results

High Titer Target		Low Titer Target		Low Titer Target Percent Positivity
Virus Name	Concentration	Virus Name	Concentration	
Flu B (Yamagata)	4.17×10^5	Flu A (H1N1)	8.4×10^3	100%
		SARS-CoV-2	3.81×10^4	100%
Flu B (Yamagata)	4.17×10^5	Flu A (H3N2)	4.2×10^5	100%
		SARS-CoV-2	3.81×10^4	100%
SARS-CoV-2	2.53×10^5	Flu A (H1N1)	8.4×10^3	100%
		Flu B (Victoria)	6.75×10^5	100%
SARS-CoV-2	2.53×10^5	Flu A (H1N1)	8.4×10^3	100%
		Flu B (Yamagata)	3.12×10^2	100%
SARS-CoV-2	2.53×10^5	Flu A (H3N2)	4.2×10^5	100%
		Flu B (Victoria)	6.75×10^5	100%
SARS-CoV-2	2.53×10^5	Flu A (H3N2)	4.2×10^5	100%
		Flu B (Yamagata)	3.12×10^2	100%

REPRODUCIBILITY

The reproducibility was evaluated at three external CLIA-waived sites with a total of eight untrained operators and one internal site with three trained operators. The reproducibility panel was composed of a panel consisting of true negative (TN), a high negative sample (HN, 0.1x LoD), a low positive (LP, 1 x LoD), and a moderate positive (MP, 5x LoD) sample for each analyte. This resulted in 165 total tests per sample level. The results are shown in the table below.

Table 8. Reproducibility Study Results

Sample	No of Positive Result/No of Total Tested (% Positive Rate)				Agreement	
	External Site 1 (2 operators)	External Site 2 (3 operators)	External Site 3 (3 operators)	Internal Site 4 (3 operators)	Total	95% CI
TN	0/30 (0%)	0/45 (0%)	0/45 (0%)	0/45 (0%)	165/165 (100%)	97.7-100.0
HN COVID	0/30 (0%)	0/45 (0%)	0/45 (0%)	0/45 (0%)	165/165 (100%)	97.7-100.0
HN Flu A	0/30 (0%)	0/45 (0%)	0/45 (0%)	0/45 (0%)	165/165 (100%)	97.7-100.0
HN Flu B	0/30 (0%)	0/45 (0%)	1/45 (2.2%)	0/45 (0%)	164/165 (99.4%)	96.7-99.9
LP COVID	30/30 (100%)	45/45 (100%)	45/45 (97.8%)	45/45 (100%)	165/165 (100%)	97.7-100.0
LP Flu A	30/30 (100%)	45/45 (100%)	44/45 (100%)	45/45 (100%)	164/165 (99.4%)	96.7-99.9
LP Flu B	30/30 (100%)	45/45 (100%)	45/45 (100%)	45/45 (100%)	165/165 (100%)	97.7-100.0

Table 8. Reproducibility Study Results

Sample	No of Positive Result/No of Total Tested (% Positive Rate)				Agreement	
	External Site 1 (2 operators)	External Site 2 (3 operators)	External Site 3 (3 operators)	Internal Site 4 (3 operators)	Total	95% CI
MP COVID	30/30 (100%)	45/45 (100%)	45/45 (100%)	45/45 (100%)	165/165 (100%)	97.7-100.0
MP Flu A	30/30 (100%)	45/45 (100%)	45/45 (100%)	45/45 (100%)	165/165 (100%)	97.7-100.0
MP Flu B	30/30 (100%)	45/45 (100%)	45/45 (100%)	45/45 (100%)	165/165 (100%)	97.7-100.0

CLIA WAIVER STUDY

The accuracy of the OSOM COVID-19/Flu A&B Combo Test was evaluated in a prospective clinical study during November 2022 and February 2025 at six intended-use CLIA-waived sites. The sites consisted of urgent care clinics and physicians' offices. A total of fourteen (14) operators, representative of CLIA-waived site personnel (intended users) with no prior laboratory experience, participated in the study without any training on the use of the test. The results obtained from the OSOM COVID-19/Flu A&B Combo Test by the intended users were compared with those obtained using an FDA-cleared RT-PCR method. This study evaluated 1,969 prospectively collected specimens. For SARS-CoV-2 detection, 265 of these specimens tested positive, and 1,704 tested negative by the FDA-cleared RT-PCR method. The comparison of OSOM COVID-19/Flu A&B Combo Test results with the comparator method results showed a PPA of 87.6% (232/265) with a 95% CI of 83.0%-91.0%, NPA of 99.8% (1,701/1,704) with a 95% CI of 99.5%-99.9%. For influenza A detection, 480 of these specimens tested positive, and 1,489 tested negative by the FDA-cleared RT-PCR method. The comparison of OSOM COVID-19/Flu A&B Combo Test results with the comparator method results showed a PPA of 86.9% (417/480) with a 95% CI of 83.6%-89.6%, NPA of 99.6% (1,483/1,489) with a 95% CI of 99.1%-99.8%. For influenza B detection, 114 of these specimens tested positive, and 1,855 tested negative by the FDA-cleared RT-PCR method. The comparison of OSOM COVID-19/Flu A&B Combo Test results with the comparator method results showed a PPA of 86.8% (99/114) with a 95% CI of 79.4%-91.9%, NPA of 99.7% (1,850/1,855) with a 95% CI of 99.4%-99.9%. A summary of these results is presented in Section 13: Clinical Performance.

A near-the-cutoff study was conducted to demonstrate the capability of untrained users to accurately test samples with concentrations near the assay cutoff. This study was conducted at three CLIA-waived intended-use sites using simulated swab samples as part of the reproducibility study. The samples were spiked with 1x LoD concentration (low positive ≈ 95% positivity) and high negative samples (0.1x LoD). The swabs were provided to the operators in blinded and randomized panels for testing with the OSOM COVID-19/Flu A&B Combo Test according to the test procedure. A total of eight (8) untrained operators participated, with each site having two or three operators. Each operator tested 15 low positive and 15 high negative samples for each virus across five nonconsecutive days. The study results demonstrated an agreement of over 99.4% with the expected outcomes. A summary of these results is presented in Section 20: Reproducibility.

Using risk analysis as a guide, analytical flex studies were conducted. The studies demonstrated that the test was not sensitive to the environmental stresses or potential user errors.

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GLOSSARY

	Caution: Federal law restricts this device to sale by or on the order of a physician
	Catalog number
	Batch code
	Use-by date
	Consult instructions for use
	*In Vitro* Diagnostic Medical Device
	Temperature limit
	Positive control
	Negative control
	Do not re-use
	Contains sufficient for <n> tests
	Attention, see instructions for use

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COVID-19/Flu A&B Combo Test

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