CLSI PROCEDURE

Product Name:	**Status™ COVID-19/Flu A&B**
Item # 33225 FDA 510K CLIA WAIVED for anterior and nasopharyngeal swab specimens	

Institution:	
Prepared By:	Date:
Title:	

Accepted By:	Date:
Title:	

Accepted By:		Date:	

Discontinued By	Date:

lifeSign

CONTENTS

SECTION 1 - TEST NAME

***Status*™ COVID-19/Flu A&B**

Rapid Immunoassay for Direct Detection and Differential Diagnosis of SARS-CoV-2, Influenza Type A, and Type B Antigens

· For In Vitro Diagnostic Use
· For Prescription Use Only
· CLIA Complexity-WAIVED for Use with Anterior Nasal and Nasopharyngeal Swab
· Certificate of Waiver is required to perform the test in a waived setting
· 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

SECTION 2 - INTENDED USAGE

The Status™ COVID-19/Flu A&B test is a lateral flow immunoassay intended for the qualitative detection and differentiation of influenza A and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly from nasopharyngeal (NP) or anterior nasal swab (ANS) specimens 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.

SECTION 3 - SUMMARY AND EXPLANATION OF TEST

Influenza is a highly contagious acute viral infection of the respiratory tract. It is a communicable disease easily transmitted from person to person through aerosol droplets excreted when sneezing and coughing. Common symptoms include high fever, chills, headache, cough, sore throat, and malaise. The type A influenza virus is more prevalent and is the primary pathogen associated with serious epidemics. The type B virus causes a disease that is generally not as severe as that caused by the type A virus.

An accurate diagnosis of influenza based on clinical symptoms is difficult because the initial symptoms of influenza are similar to those of numerous other illnesses. Therefore, it can be confirmed only by laboratory diagnostic testing. Early differential diagnosis of influenza type A or type B can allow for proper treatment with appropriate antiviral therapy while reducing the incidence of inappropriate treatment with antibiotics. Early diagnosis and treatment are of particular value in a clinical setting where an accurate diagnosis can assist the healthcare professional with the management of influenza patients who are at risk for complications.

In December 2019, a cluster of atypical pneumonia patients epidemiologically linked to a wet market in Wuhan (Hubei province, China) was detected. Initially, the novel coronavirus was named 2019-nCoV. Later it was named the SARS-CoV-2 virus, as it is very similar to the one that caused the outbreak of severe acute respiratory disease (SARS) in 2003. At the end of January 2020, the World Health Organization (WHO) declared the new infectious disease COVID-19 a global emergency.

On 11 March 2020, the WHO recognized the new infectious disease as a pandemic. COVID-19 has demonstrated the capability of spreading rapidly, leading to significant impacts on the healthcare system and causing societal disruption. The ongoing COVID-19 pandemic has infected millions of people worldwide. To respond effectively to the COVID-19 outbreak, rapid detection of cases, stringent performance assessment, and increase in the current diagnostic capacity are still urgently needed. The symptoms of COVID-19 are similar to those of other viral respiratory disease and include fever or chills, cough, shortness of breath or difficulty of breathing, fatigue, muscle or body aches, headache, the new loss of taste or smell, sore throat, congested or runny nose, nausea or vomiting or diarrhea, etc. As the early symptoms of COVID-19 are similar to those of seasonal Influenza A or B, a rapid detection test to specifically diagnose symptomatic patients is urgently needed.

The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with 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.

SECTION 4 - PRINCIPLE OF TEST

The Status™ COVID-19/Flu A&B test is a lateral flow immuno-chromatographic assay which utilizes the chemical extraction of viral antigens followed by solid-phase immunoassay technology. The **Status™ COVID-19/Flu A&B** test is designed to detect antigens from SARS-CoV-2, influenza A, and /or influenza B in nasopharyngeal or anterior nasal swab specimens from individuals with signs and symptoms of respiratory infection. It is intended to aid in the rapid differential diagnosis of SARS-CoV-2, influenza A, and /or influenza B viral infections. The **Status™ COVID-19/Flu A&B** test is validated for use with direct specimens without transport media.

In the test procedure, a nasopharyngeal or anterior nasal swab specimen is collected and placed into extraction reagent in the Extraction Well of the test device for one minute. During this time, the antigen is extracted from disrupted virus particles. The test device is then raised, tapped, and laid back down onto a level surface. Through this simple action, the solution of extracted specimen flows onto the test strip and migrates through the pads and membrane of the test strip. The pads contain detector antibodies conjugated to gold dye and the membrane contains immobilized capture antibodies. If SARS- CoV-2, influenza A, and/or influenza B antigens are present in the specimen, they will react with anti-SARS-CoV-2 antibody coupled to gold dye particles and/or anti-influenza antibody coupled to gold dye particles, migrate through the membrane as antigen/antibody-dye complexes, bind to the immobilized capture antibody line(s) on the membrane, and generate a colored line in the specific test line position. The rest of the sample and unbound/bound dye complexes continue to migrate to the Control line position (Ctrl), where immobilized antibodies to the anti-SARS-CoV-2 and anti-influenza antibodies capture the dye complexes and form the Control line. Formation of the Control line serves as an internal control to demonstrate that test reagents are functional, antibody-dye conjugates in the dye pad have been hydrated and released and that sufficient sample has been applied to allow for migration through the Test and Control lines. If the Control line does not appear within the designated incubation time, the result is invalid, and the test should be repeated using a new test device and specimen.

Status™ COVID-19/Flu A&B test has three Test lines, one for SARS-CoV-2(CoV19), one for influenza A (Flu A), and one for influenza B (Flu B). The three Test lines allow for the separate and differential identification of SARS-CoV-2, influenza A, and/or B from a single specimen. If any Test line appears in the test result window, together with the Control line, the test result is positive for SARS-CoV-2 and/or influenza. The test detects, but does not differentiate, between the SARS-CoV and SARS-CoV-2 viruses

SECTION 5 - KIT CONTENTS/MATERIALS PROVIDED AND STORAGE

Each ***Status*™ COVID-19/Flu A&B** kit contains enough reagents and materials for 25 tests. The following components are included in a kit.

- **Status COVID-19/Flu A&B** test devices (25): The test strip in each device contains mouse monoclonal antibodies to nucleocapsid protein of influenza A, influenza B and SARS- CoV-2. The device is individually pouched.
- Extraction Reagent in capsules (25): For use with swab specimens; 300 µL of Phosphate buffer with detergents and preservative
- Sterile Swabs (25): For anterior nasal and nasopharyngeal swab specimen collection
- Positive Control Swab (1): Influenza A, B, and SARS-CoV-2 antigen (non-infective recombinant nucleocapsid protein)
- Negative Control Swab (1): Inactivated Group B Streptococcus antigen (non-infective)
- Package Insert /Instructions for use (1)
- Quick Reference Instructions (1)

Storage and Stability

The ***Status*™ COVID-19/Flu A&B** test should be stored at 2-30°C (35-86°F) in the original sealed pouch, away from direct sunlight. Kit contents are stable until the expiration date printed on the pouch or box. **DO NOT** open foil pouch until ready to use test.

SECTION 6 - MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- PPE

SECTION 7 - 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 5 days or no symptoms at all.
• Ensure that there is sufficient lighting for testing and interpretation of results.
• Do not interchange the kit contents from different lots.
• Do not use this test for individuals who recently received nasally administered influenza A or influenza B vaccine, as they may cause false positive test results after vaccination.
• Wear a safety mask or other face-covering when collecting a specimen.
• Test components are single use. Do not re-use.
Once opened, the test device should be used within 4 hours when exposed to ambient temperature and humidity.
• Do not read test results before 15 minutes or after 20 minutes. Results read before 15 minutes or after 20 minutes may lead to a false positive, false negative, or invalid result.
• **The Status™ COVID-19/Flu A&B** test is only intended for use with direct nasopharyngeal or anterior nasal swab specimens and is not validated or authorized for use with viral transport media.
• Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
• Dispose of containers and unused contents in accordance with federal, state, and local regulatory requirements.
• Use only the swabs provided for collecting specimens. Other swabs may not work properly.
• Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled.
• Wear disposable gloves while handling kit reagents or specimens and thoroughly wash hands afterwards.
• All specimens should be handled as if they are capable of transmitting disease. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens and test devices.
• The **Status™ COVID-19/Flu A&B** test device should remain in its original sealed pouch until ready for use. Do not use the test if the seal is broken or the pouch is damaged.
• If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, the specimen should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health departments for testing.
• For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19
• Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your [e.g., 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 [e.g., 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.

Specimen Collection and Preparation

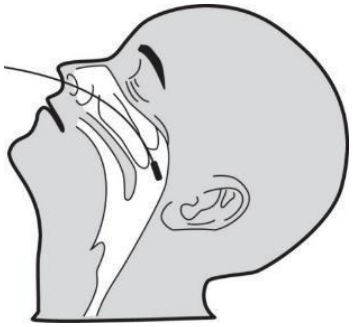
Good sample collection is the most important first step for an accurate test result. Therefore, carefully follow the instructions below for collection of nasopharyngeal or anterior nasal swab specimens to obtain as much secretion as possible.

Inadequate or inappropriate specimen collection, storage, and transport are likely to yield false negative test results. Training in specimen collection is highly recommended because of the importance of specimen quality.

- To collect nasopharyngeal or anterior nasal swab specimens, only the swab provided in the **Status™ COVID-19/Flu A&B** test kit should be used.
- Use fresh samples for best performance. Freshly collected specimens should be tested immediately.
- Transport media should not be used. This test has not been validated or authorized using viral transport media.

To collect Nasopharyngeal Swab Specimen

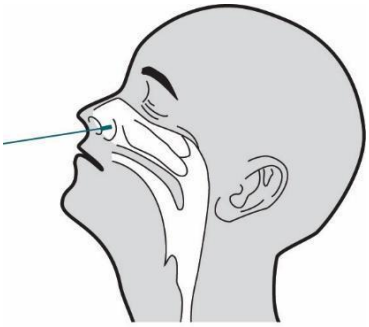
Use a flocked swab provided in the ***Status*™ COVID-19/Flu A&B** kit only. Tilt patient's head back 70 degrees. Gently and slowly insert the swab with a flexible shaft through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. Swab should reach depth equal to distance from nostrils to outer opening of the ear. Gently rub and roll the swab. Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the swab is saturated with fluid from the first collection. If a deviated septum or



blockages create difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.

To collect Anterior Nasal Swab Specimen

Use the flocked swab provided in the **Status™ COVID-19/Flu A&B** kit only. Insert the entire soft end of the swab into the patient's nostril no more than ¾ of an inch (1.5 cm) into the patient's nose. Slowly rotate the swab, gently pressing against the inside of the patient's nostril at least 4 times for a total of 15 seconds. Get as much secretion as possible on the soft end of the swab. Gently remove the swab. Using the same swab, repeat in the second nostril with the same end of the swab.



SECTION 9 - QUALITY CONTROL AND ASSURANCE

Internal Quality Control:

Each ***Status*™ COVID-19/Flu A&B** test device has built-in procedural controls. The Control line at the C position can be considered as an internal positive procedural control; i.e., a proper amount of sample was used, sample was properly added to the Extraction Well, sample migrated properly, and the reagent system worked properly. A distinct reddish-purple Control line should always appear if the test has been performed correctly.

If the Control line does not appear, the test result is invalid and a new test should be performed. If the problem persists, contact LifeSign at 800-526-2125 or 732-246-3366 for technical assistance.

A clear background in the Test Result Window is considered an internal negative procedural control. If the test is performed correctly and the ***Status*™ COVID-19/Flu A&B** test device is working properly, the background in the Test Result Window will be clear, providing a distinct result.

External Quality Control:

Good laboratory practice includes the use of external controls to ensure proper kit performance. It is recommended that external control testing be performed with each new operator and before using a new lot or shipment of ***Status*™ COVID19/Flu A&B** kits to confirm the expected Q.C. results, using the external control swabs provided in the test kit. The frequency of additional QC tests should be determined according to your laboratory's standard Q.C. procedures and local, State and Federal regulations or accreditation requirements. Upon confirmation of the expected results, the kit is ready for use with patient specimens. If external controls do not perform as expected, do not use the test results. Repeat the tests or contact LifeSign Technical Services @ 800-526-2125. The built-in reddish purple Control line indicates only the integrity of the test device and proper fluid flow.

The ***Status*™ COVID-19/Flu A&B** kit contains two external control swabs. Test the control swabs in the same manner as patient specimens. When the positive control is tested, reddish purple lines appear at the C as well as A, B, and COV-19 positions. When the negative control is tested, a reddish purple line appears at the C position only.

If the controls do not perform as expected, do not report patient results. Repeat test using a new test device.

The use of positive and negative controls from other commercial kits has not been established with ***Status*™ COVID-19/Flu A&B** test.

SECTION 10 - TEST PROCEDURE

1. Tear the tab off the Extraction Reagent capsule and squeeze it to dispense all of the solution into the Extraction Well of the test device.

2. Insert the specimen swab into the Swab Stand in the Extraction Well and rotate it 3 times to mix the specimen. Incubate for 1 minute with the swab in Extraction Well. Rotate swab 3 times again to mix the specimen. Remove from Swab Stand and discard the swab.

Note: False negative results can occur if the swab is not rotated as instructed above.

3. Raise the device upright (see diagram). Let it stand for 1-2 seconds. Gently tap the device to ensure that the liquid flows into the hole. Lay the device back down onto the flat surface. Start timing – 15 minutes.

4. Read results at 15 minutes. Results should not be read after 20 minutes.

Note: To ensure proper test performance, it is important to read results at 15 minutes. False positive or false negative results can occur if the test is not read between 15 and 20 minutes.

Procedural Notes

- The test procedure below must be followed to obtain accurate and reproducible results.
- Reagents, specimens, and devices must be at room temperature (18-30°C) for testing.
- Do not open the foil pouch until you are ready to perform the test.
- Label the device with the patient identification or control to be tested.
- Place test device on a level surface.

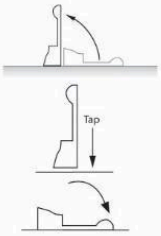
❶ 

Tear the tab off the Extraction Reagent Capsule and dispense entire contents into the Extraction Well.

❷ 

Insert the specimen swab in the Swab Stand.

- **Rotate** swab 3 times to mix the specimen.
- **Let stand** 1 minute.
- **Rotate** swab 3 times again and discard the swab.

❸ 

Raise the device upright and **let stand** 1–2 seconds.

Gently **tap** the device to ensure the liquid flows into the hole.

Lay the device back down.

Set a timer for 15 minutes.

❹ **Read test results at 15 minutes.**

NOTE: False positive or false negative results can occur if the test is not read between 15 and 20 minutes.

SECTION 11 - INTERPRETATION OF RESULTS

Positive: Determination of a positive result is made at fifteen (15) minutes. A reddish purple Control line (C position) and a reddish purple Test line (Flu A, Flu B or CoV19 position) indicate that Influenza A, B and/or SARS-CoV-2 antigen has been detected. Lines at the A and C positions indicate the presence of Influenza type A viral antigen, lines at the B and C positions indicate the presence of Influenza type B viral antigen, and lines at the CoV19 and C positions indicate the presence of SARS-CoV-2 viral antigen in the specimen. A positive result does not rule out co-infections with other pathogens or identify any specific influenza A virus subtype.

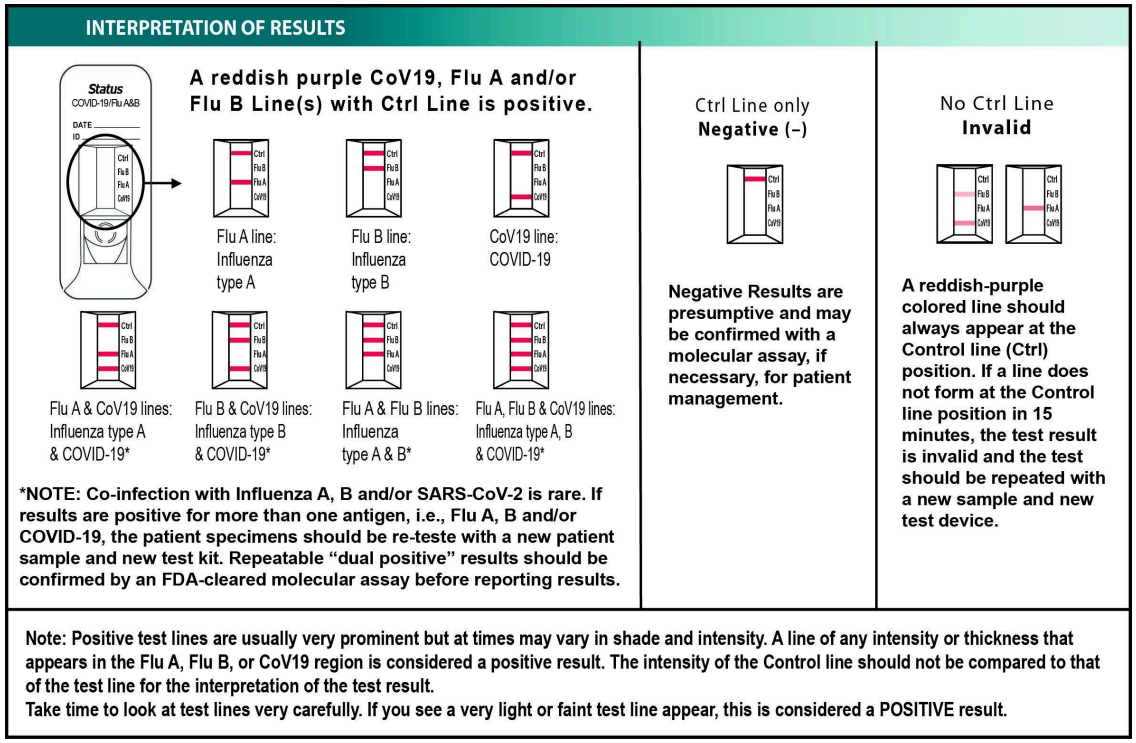
Note: The Test line (reddish purple line) may vary in shade and intensity (light or dark, weak or strong) depending on the concentration of antigen detected. The intensity of the Control line should not be compared to that of the Test line for the interpretation of the test result. Even a light or faint Test line must be interpreted as a positive result. Product Name:

Negative: A reddish purple Control line (C position) only, with no Test line at the A, B, CoV19 positions, indicates that Influenza A, B antigen or SARS-CoV-2 antigen has not been detected. A negative result does not exclude influenza viral or SARS-CoV-2 viral infection. Determination of negative results should not be made before 15 minutes.

Negative results are presumptive and may need to be confirmed with a molecular assay.

Invalid: A reddish purple line should always appear at the Control line position (C 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 ***Status*™ COVID19/Flu** test device. If the problem still persists, contact Lifesign's Technical Suppprt at 800-526-2125.

NOTE: Co-infection with Influenza A, B and/or SARS-CoV-2 is rare. If results are positive for more than one antigen, i.e., Flu A, B and/or COVID-19, the patient specimens should be re-tested.



SECTION 12 - LIMITATIONS

The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between September 2023 and October 2024. 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.

- This test is read visually. Because these lines can be very faint, users with conditions affecting their vision- such as farsightedness, glaucoma, or color blindness- are encouraged to seek assistance to interpret results accurately (e.g., reading glasses, additional light source, or another person). This test has not been validated for use by those with color impaired vision.
- 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 COVID-19 as compared to a molecular test, especially in samples with low viral load.
- This test provides a presumptive negative result that should be confirmed using an independent highly sensitive molecular test to make well-informed clinical decisions.
- Use of **Status™ COVID-19/Flu A&B** is limited to laboratory personnel and CLIA-waived users.
- These contents of this test are to be used as a qualitative test and do not provide information on the viral concentration present in the specimen.
- This test detects both viable (live) and nonviable SARS-CoV-2, influenza A, and influenza B. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture 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 is collected, handled, or transported improperly.
- Positive test results do not rule out co-infections with other respiratory pathogens.
- Positive test results do not identify specific coronavirus, influenza A virus and influenza 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.
- Performance of the **Status™ COVID-19/Flu A&B** test has not been established for monitoring antiviral treatment of influenza and SARS-CoV-2.
- The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection.
- The performance of this test has not been evaluated for immunocompromised individuals.
- The performance of the **Status™ COVID-19/Flu A&B** test was not evaluated with samples collected in viral transport media and should not be used with this test.
- 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 activity when prevalence is moderate to low.
- FluMist/FluMist Quadrivalent (Live Attenuated Influenza Vaccine, Intranasal) may interfere with this test, resulting in false positive influenza A and/or influenza B results.

SECTION 13 - EXPECTED RESULTS and SECTION 15- PERFORMANCE CHARACTERISTICS

The rate of positives in COVID-19 testing varies depending on many factors, including the specimen collection method, the disease prevalence, and the geographic location. The prevalence of influenza varies every year and the rate of positives in influenza testing varies depending on many factors, including the specimen collection method, the test method used, the disease prevalence, and the geographic location. The expected values based on previous *Status* Flu A&B results are 30.3% for influenza A and 13.8% for influenza B during the 2007-2009 prospective clinical study, and were 33.6% for influenza A and 9.8% for influenza B during the 2014-2016 prospective clinical study.

Clinical Performance – Nasopharyngeal swab specimen A prospective study was conducted at six (6) CLIA-waived U.S. sites from September 2023 to October 2024. Nasopharyngeal (NP) swab specimens were collected from 550 patients aged 2 years and older who presented within five days of respiratory symptom onset consistent with SARS-CoV-2, influenza A, or influenza B. Sample collection and testing were performed by healthcare professionals who had no prior experience in 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. One NP swab was tested using an FDA-authorized RT-PCR comparator assay, and the other with the Status™ COVID-19/Flu A&B test. Thirteen (13) specimens were excluded due to not meeting inclusion criteria, resulting in 537 specimens included in the final performance analysis. Test performance was evaluated by comparison to RTPCR results.

Nasopharyngeal Swab Performance

***Status*™ COVID-19/Flu A&B – compared to reference PCR: SARS-CoV-2:**

Positive Percent Agreement (PPA) = 95.5 % (95 % CI: 91.4 % to 97.7 %) Negative Percent Agreement (NPA) = 99.7 (95 % CI: 98.4% to 99.9 %)

***Status*™ COVID-19/Flu A&B – compared to reference PCR: Influenza A**

Positive Percent Agreement (PPA) = 94.1 % (95 % CI: 84.1 % to 98.0 %) Negative Percent Agreement (NPA) = 99.4% (95 % CI: 98.2 % to 99.8 %)

***Status*™ COVID-19/Flu A&B – compared to reference PCR: Influenza B**

Positive Percent Agreement (PPA) = 92.7 % (95 % CI: 82.7 % to 97.1 %) Negative Percent Agreement (NPA) = 100.0 % (95 % CI: 99.2 % to 100.0 %)

Anterior Swab Performance

Status™ COVID-19/Flu A&B performance compared to reference PCR: SARS-CoV-2

Positive Percent Agreement (PPA) = 97.4 % (95 % CI: 92.7 % to 99.1 %) Negative Percent Agreement (NPA) = 100.0 % (95 % CI: 98.9 % to 100.0 %)

Status™ COVID-19/Flu A&B performance compared to reference PCR: Influenza A

Positive Percent Agreement (PPA) = 91.5 % (95 % CI: 80.1 % to 96.6 %) Negative Percent Agreement (NPA) = 99.5 % (95 % CI: 98.2 % to 99.9 %)

Status™ COVID-19/Flu A&B performance compared to reference PCR: Influenza B

Positive Percent Agreement (PPA) = 90.2 % (95 % CI: 77.5 % to 96.1 %) Negative Percent Agreement (NPA) = 99.8 % (95 % CI: 98.9 % to 100.0 %)

Analytical Performance Limit of Detection (LOD)

The limit of detection (LoD) of the Status™ COVID-19/Flu A&B test was defined as the lowest concentration of SARS-CoV-2, influenza A, and influenza B at which ≥95 % of replicates tested positive. LoD was determined through preliminary and confirmatory studies. In the preliminary study, serial 10-fold dilutions of heat-inactivated SARS-CoV-2 and live influenza A and B viruses were prepared in pooled negative clinical matrix (NCM) and tested in triplicate using three device lots. For each test, 50 µL of sample was applied to the swab and processed per IFU instructions. The lowest concentration that produced at least 95 % positive results was identified as the LoD. Co-spiking the analytes into the negative nasal specimen does not affect their LoD.

SARS-CoV-2, USA-WA1/2020	3.39×10^4	1.70×10^3	58/60	96.7
SARS-CoV-2 Lineage BA.5; Omicron Variant, USA/COR-22- 06 3113/2022	2.81×10^3	1.41×10^2	57/60	95.0
Influenza A, H1N1, Victoria/2570/19	1.56×10^1	0.78	59/60	98.3
Influenza A, H3N2, Darwin/9/21	1.25×10^1	0.63	57/60	95.0
Influenza A, H1N1, Victoria/4897/22	3.89×10^1	1.95	59/60	98.3
Influenza B, Victoria, Austria/1359417/2	9.40×10^2	4.70×10^1	58/60	96.7
Influenza B, Yamagata, Phuket/3073/13	1.30×10^1	0.65	60/60	100.0

Analyte	LoD		# Positive/ # Total	Percent Detected (%)
	IU/mL	IU/Swab		
The First WHO International Standard for SARS-CoV-2 Antigen (NIBSC 21/368)	250	12.5	40/40	100

The first WHO International Standard for SARS-CoV-2 Antigen (NIBSC 21/368) was also tested using the same method to determine the LoD of SARS-CoV-2 antigen. The LoD of the standard is provided in the table above.

High-dose Hook Effect A high-dose hook effect was not detected in the Status™ COVID-19/Flu A&B test, for the SARS-CoV-2, Influenza A and B viral strains at the concentration.

SARS-CoV-2 and Influenza A&B virus -Concentration (TCID50/mL)

SARS-CoV-2, USA-WA1/2020 Concentration - 3.39 × 107

SARS-CoV-2 Lineage BA.5; Omicron Variant, USA/COR-22-063113/2022 – Concentration- 2.53 × 106

Influenza A, H1N1, A/Baltimore/JH-22377/2022 – Concentration- 1.6 × 109

Influenza A, H3N2, A/Baltimore/JH-0440/2022 – Concentration - 2.8 × 107

Influenza A, H1N1, Victoria/2570/19 – Concentration - 4.68 × 104

Influenza A, H3N2, Darwin/9/21 – Concentration- 3.74 ×104

Influenza B, Victoria, Austria/1359417/21 – Concentration- 2.82 × 106

Influenza B, Yamagata, Texas/6/11 –Concentration- 3.80 × 106

Influenza B, Yamagata, Phuket/3073/13 – Concentration- 3.89 × 10

References

1. Shaw MW, Arden NH and Massab HF. New aspects of influenza viruses. Clin. Microbiol. Rev. 5: 74-92 (1992)

2. WHO recommendations on the use of rapid testing for influenza diagnosis, July 2005.

3. Design Considerations for Pivotal Clinical Investigations for Medical Devices: Guidance for Industry, Clinical Investigators, Institutional Review Boards and Food and Drug Administration Staff, November 7, 2013 (Page 45)

SECTION 16 - TECHNICAL ASSISTANCE

If you have any questions regarding the use of this product, please contact LifeSign's Technical Support via email: techservice@lifesignmed.com, or via phone at 800-526-2125 or 732-246-3366)

Certification of Training

This is to verify that personnel responsible for running _____ test at _____ have been thoroughly in-serviced on the test and the test procedure(s).

This has included:

Review of the package insert

Demonstration of the product assay

Successful performance of the test and interpretation of results

Names of the personnel who have been trained with the above test and are responsible for reporting patient results:

Print Name	Signature	Date

Signature(s) of those responsible for personnel and testing:

_____ _____

Signature Date

_____ _____

Signature Date

_____ _____

Signature Date

lifeSign

Quality Control

Name of Facility _____

Use this cover sheet with each new shipment and/or with each new kit lot

Product _____ Lot# _____ Exp Date _____

Date Received _____ Rec'd By _____

	Date	Positive Control	Negative Control	Initials
Initial QC				
Additional QC				
Additional QC				
Additional QC				
Additional QC				
Additional QC				
Additional QC				

Reviewed by _____ Date _____

Testing Personnel Competency Assessment

Test _____

Procedure	Satisfactory	Unsatisfactory	Not Applicable	Comments/Corrective Action(s)
Observation of Test performance				
Patient Sample Preparation				
Specimen Handling/Processing				
Testing				
Recording/Reporting Results				
Assessment of Test Performance Using Known				
Review of Records				
Patient/Quality Control Log Sheet Records				
Proficiency Testing Records				
Assessment of Problem Solving Skills				

(Attach all supporting documents)

Evaluator: _____ Date: _____

Testing Personnel: _____ Date: _____