P-5382

Status™ COVID-19/Flu

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

For *In Vitro* Diagnostic Use Only
For Rx Use Only
For use under an Emergency Use Authorization only

Catalog No. 33225

Intended Use

***Status*™ COVID-19/Flu** test is a lateral flow immunoassay intended for the *in vitro* rapid, simultaneous qualitative detection and differentiation of nucleocapsid antigen from SARS-CoV-2, influenza A and influenza B directly from nasopharyngeal swab specimens obtained from individuals, who are suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider, within the first five days of onset of symptoms. 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 identification of nucleocapsid antigens of SARS-CoV-2, influenza A and influenza B, 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 nasopharyngeal swab samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but the 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 definite cause of the disease. Laboratories within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities.

Negative SARS-CoV-2 results should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management. 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. Negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Negative influenza A and B test results should be treated as presumptive. It is recommended these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions.

Performance characteristics for influenza A and B were established during the 2007-2009 and the 2014-2016 influenza seasons when influenza A/H1N1, A/H1N1 pandemic, A/H3N2, influenza B/Victoria lineage, and B/Yamagata lineage were the predominant influenza viruses in circulation according to the Flu Activity & Surveillance reports from the CDC. When other influenza viruses are emerging, performance characteristics may vary.

The performance of this test for SARS-CoV-2 was established based on the evaluation of a limited number of clinical specimens collected between September 2020 and January 2021. 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 and their prevalence, which change over time.

If infection with a novel influenza virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. A viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

The ***Status*™ COVID-19/Flu** test is intended for use by medical professionals and laboratory personnel trained to perform the test. The ***Status*™ COVID-19/Flu** test is only for use under the Food and Drug Administration's Emergency Use Authorization.

Summary and Explanation

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.[1] 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.[2]

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.

Principle of Procedure

The Status™ COVID-19 /Flu test is a modification of the FDA 510(k) cleared device, Status Flu A&B, initially cleared on 11/10/2010 (k083746). The modification of the Status™ COVID-19/Flu device consists of the addition of a test line of monoclonal antibody and a pad containing monoclonal antibody-dye conjugate for the detection of SARS-CoV-2 antigen from nasopharyngeal (NP) swab patient specimen. The Status™ COVID-19/Flu test is intended to aid in the rapid differential diagnosis of Influenza A, B, and SARS-CoV-2 viral infection. The ***Status*™ COVID-19/Flu** 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** test is designed to detect antigens from SARS-CoV-2, influenza A, and /or influenza B in nasopharyngeal swab specimens from individuals with signs and symptoms of respiratory infection, suspected of COVID-19 or flu by their healthcare provider, within the first five days of onset of symptoms. 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** test is validated for use with direct specimens without transport media.

In the test procedure, a nasopharyngeal 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 (C), 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** test has three Test lines, one for SARS-CoV-2, one for influenza A, and one for influenza 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.

Reagents

Materials Provided

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

- ***Status*** **COVID-19/Flu** 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 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 Instruction (1)

Materials Required, But Not Provided

- Timer

Precautions/Warnings

- For *in vitro* diagnostic use only.
- For prescription use only.
- This product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by laboratories certified under 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.
- 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

- Do not use after the expiration date printed on the outside of the box.
- The Status COVID-19/Flu test is only intended for use with direct nasopharyngeal specimens and is not validated or authorized for use with viral transport media.
- Do not reuse used test devices, swabs, extraction tubes, or control swabs.
- Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
- To obtain accurate results, the Package Insert instructions must be followed.
- 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.
- Extraction Reagent is slightly caustic. Avoid contact with eyes, sensitive mucous membranes, cuts, abrasions, etc. If the reagent comes in contact with skin or eyes, flush with a large volume of water.
- 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** 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. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

Storage and Stability

The ***Status*™ COVID-19/Flu** test may 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.

Specimen Collection and Preparation

- 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 specimens, only the swab provided in the ***Status*™ COVID-19 /Flu** test kit should be used.
- Use fresh samples for best performance. Freshly collected specimens should be tested immediately. If necessary, swab samples can be stored for up to 4 hours at room temperature or up to 8 hours at 2-8°C.
- Transport media should not be used. This test has not been validated or authorized using

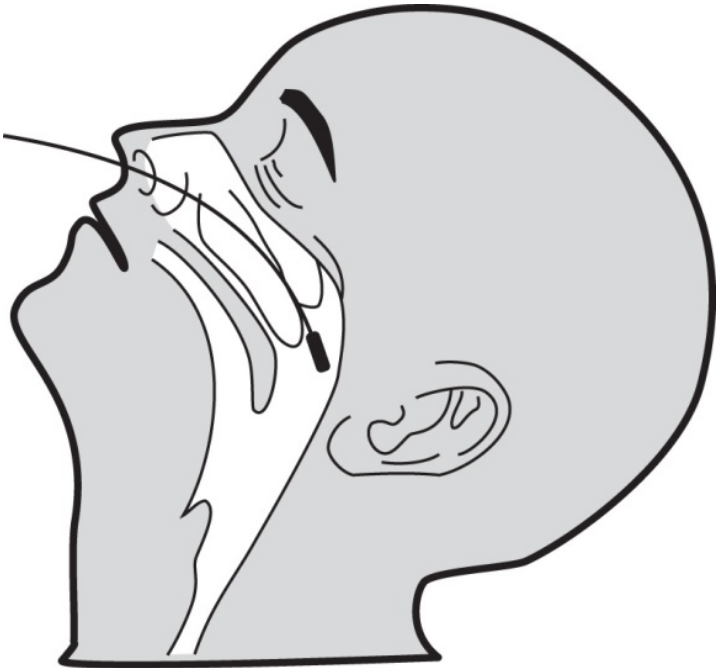
viral transport media.

Specimen Collection Procedure

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

To collect Nasopharyngeal Swab Specimen

Use a flocked swab provided in the ***Status*™ COVID-19/Flu kit** only. Tilt patient's head back 70 degrees. Gently and slowly insert a minitip 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 minitip 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.



Test Procedure

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.

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.

❶

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

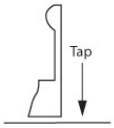
❷

Insert the specimen swab in the Swab Stand.

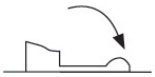
- **Rotate** swab 3 times to mix the specimen.
- **Let stand** 1 minute.
- **Rotate** swab 3 times again and discard the swab.

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.

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.

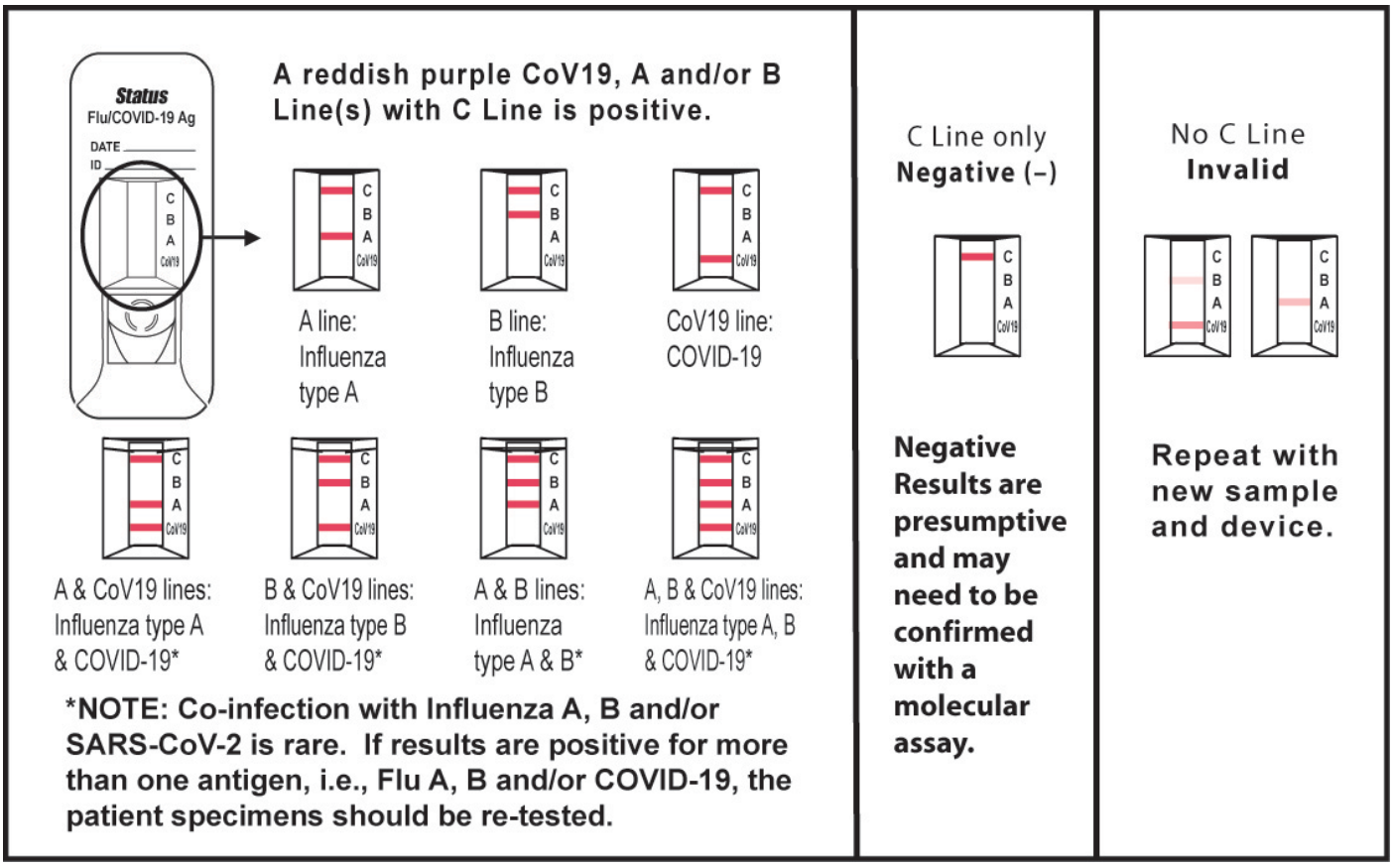
Note: *The Test line (reddish purple line) may vary in shade and intensity (light or dark, weak or strong) depending on the concentration of antigen detected. The intensity of the Control line should not be compared to that of the Test line for the interpretation of the test result. Even a light or faint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

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*™ COVID-19/Flu test device.

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.



Limitations

- A negative test result does not exclude infection with SARS-CoV-2, influenza A, or B. **Negative test results are presumptive and may need to be confirmed with a molecular**

test. Therefore, the results obtained with the ***Status*™ COVID-19/Flu** test should be used in conjunction with clinical findings to make an accurate diagnosis. Additional testing is required to confirm the absence of infection, in consultation with state or local public health departments.

- This test detects both viable (live) and non-viable SARS-CoV-2, influenza A, and B. Test performance depends on the amount of virus (antigen) in the specimen and may or may not correlate with viral culture or molecular assay results performed on the same specimen.
- 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.
- Positive test results do not rule out co-infections with other pathogens.
- Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
- Positive test results do not identify specific influenza A virus subtypes.
- If differentiation of specific SARS or influenza A subtypes and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- ***Status*™ COVID-19/Flu** uses highly target epitope specific monoclonal antibodies. As in most immunoassays, it may fail to detect, or detect with less sensitivity, influenza A viruses that have undergone minor amino acid changes in the target epitope region.
- Performance of the ***Status*™ COVID-19/Flu** test has not been established for monitoring antiviral treatment of influenza and SARS-CoV-2.
- Performance of the ***Status*™ COVID-19/Flu** test has not been established for novel variants of SARS-CoV-2.
- Performance characteristics for influenza A were established when influenza A/H3 and A/H1 were the predominant influenza A viruses in circulation. When other influenza A viruses emerge, performance characteristics may vary.
- The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection.
- This test cannot rule out diseases caused by other bacterial or viral pathogens.
- The performance of this test has not been evaluated for specimen types other than those specified in the Intended Use.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between September 2020 and January 2021. 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 and their prevalence, which change over time.
- The performance of this test has not been evaluated for immunocompromised individuals.
- The performance of the ***Status*™ COVID-19/Flu** test was not evaluated for SARS-CoV-2 detection with samples collected in viral transport media and should not be used with this test.
- Children tend to shed influenza virus more abundantly and for longer periods of time than adults. Therefore, testing specimens from adults will result in lower sensitivity than testing specimens from children.

- 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.
- Individuals who received nasally administered influenza A vaccine may produce positive test results for up to three days after vaccination.
- The *Status*™ COVID-19/Flu test can distinguish among influenza A, B and SARS-CoV-2 viruses, but it cannot differentiate influenza subtypes.

User Quality Control

Internal Quality Control:

Each ***Status*™ COVID-19/Flu** test device has built-in 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** 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*™ COVID-19/Flu** kits to confirm the expected Q.C. results, using the external controls provided in the kit. The frequency of additional Q.C. 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. The built-in reddish purple Control line indicates only the integrity of the test device and proper fluid flow.

The ***Status*™ COVID-19/Flu** 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 CoV19 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.

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

Expected Values

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.

CONDITIONS OF AUTHORIZATION FOR THE LABORATORY AND PATIENT CARE SETTINGS

The Status™ COVID-19/Flu 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-authorizationsmedical-devices/vitro-diagnostics-euas.

However, to assist in using the Status™ COVID-19/Flu test ("your product" in the conditions below), the relevant Conditions of Authorization are listed below:

•Authorized laboratories[1] using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

•Authorized laboratories using your product must use your product as outlined in the "Status™ COVID-19/Flu" Instructions for Use and Quick Reference Instructions. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other 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.

[1] 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 high, moderate, 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." as "authorized laboratories."

•Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and (via email: technical@lifesignmed.com, or via phone by contacting LifeSign Customer Support Services at 800-526-2125 or 732-246-3366) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.

•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.

•Princeton BioMeditech Corp., 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.

Performance Characteristics

Clinical Performance

A prospective study was performed in which with one hundred twenty five (125) direct nasopharyngeal swabs were sequentially enrolled (September 2020 and January 2021) and tested fresh. The samples were collected from symptomatic patients suspected of infection with COVID-19, at four Point of Care (POC) CLIA waived clinical sites. To be enrolled in the study, patients had to present at the participating study site with signs and symptoms of respiratory infection generally observed from SARS-CoV-2, influenza A and/or influenza B, during the study period. Patients presenting within five (5) days of symptom onset were included in the study. Three nasopharyngeal swabs were collected from each patient; one swab to be tested using a comparator method for the detection of SARS-CoV-2, an FDA Emergency Use Authorized RT-PCR assay for the detection of SARS-CoV-2 and two additional swabs to be tested at the study site. One swab was tested with ***Status*™ COVID-19/Flu** test and one swab was tested with the comparator method for Flu A and B detection, *Status* Flu A&B.

SARS-CoV-2 Performance (*Status*™ COVID-19/Flu)

Patient Demographics

Patient demographics (age, the elapsed time from date of symptom onset) are available for the 125 patients participating in this study. COVID-19 Positive results are broken down by age and days post symptom onset in the tables below.

Patient Demographics (COVID-19 positive = 46)

Age	*Status* COVID-19 Ag/Flu A&B		
	Total #	Total Positive	Prevalence
≤ 5 years	0	0	N/A
6 to 21 years	16	9	56.3 %
22 to 59 years [1)]	85	28	32.9 %
≥60 years [2)]	22	9	40.9 %
Unknown [3)]	2	0	N/A

1) Two patients were *Status*™ COVID-19/Flu negative and Positive by reference extracted RT-PCR.
2) One patient was *Status*™ COVID-19/Flu negative and Positive by reference extracted RT-PCR.
3) Two patients did not provide age information.

Specimen Positivity Breakdown Based on Days Post Onset (COVID-19 positive = 46)

Days Posts Symptom Onset	# Specimens Tested	# Positive Specimens	%Positive
0[1)]	27	16	59.3%
1	43	13	30.2%
2	25	6	24.0%
3	14	6	42.9%
4	10	5	50.0%
5[2)]	6	0	0.0%

1) Two specimens were *Status*™ COVID-19/Flu negative and Positive by reference extracted RT-PCR.
2) One specimen was *Status*™ COVID-19/Flu negative and Positive by reference extracted RT-PCR.

***Status*™ COVID-19/Flu** performance compared to reference PCR: COVID-19 (SARS-CoV-2)

		Reference Extracted RT-PCR: SARS-CoV-2			Performance (95%CI)
		Positive	Negative	Total	
Status™ COVID-19 /Flu	SARS-CoV-2 Positive	46	0	46	Sensitivity: 93.9% 95% CI:83.5% to 97.9%
	SARS-CoV-2 Negative	3	76	79	Specificity: 100% 95% CI: 95.2% to 100.0%
Total		49	76	125	

Sensitivity: 93.9 % (95% CI: 83.5% to 97.9%)
Specificity: 100.0 % (95% CI: 95.2 % to 100.0 %)
Positive Predictive Value: 100.0 %
Negative Predictive Value: 96.2 % (95% CI: 89.4 % to 98.7 %)

Influenza A&B performance (*Status*™ COVID-19/Flu)

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

		Reference *Status* Flu A&B: Influenza A			Performance (95%CI)
		Positive	Negative	Total	
Status™ COVID-19 /Flu	Influenza A Positive	0	0	0	NA
	Influenza A Negative	0	89	89	NPA: 100% 95% CI: 95.9% to 100.0%
Total		0	89	89	

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

		Reference *Status* Flu A&B: Influenza B			Performance (95%CI)
		Positive	Negative	Total	
Status™ COVID-19 /Flu	Influenza B Positive	0	0	0	NA
	Influenza B Negative	0	89	89	NPA: 100% 95% CI: 95.9% to 100.0%
Total		0	89	89	

In the absence of fresh clinical Influenza A or B positive specimens, archived specimens in VTM (Remel M6 media) were confirmed positive using Cepheid Xpert or BioFire Filmarray. The samples were tested to confirm comparable performance between the *Status* COVID-19 Ag/Flu A&B test and the *Status* Flu A&B test. Results from the testing of ten (10) influenza A positive samples and eleven (11) influenza B positive samples were combined and analyzed.

Status COVID-19 Ag/Flu A&B performance compared to *Status* Flu A&B: Influenza A

		Status Flu A&B: Influenza A			Performance (95%CI)
		Positive	Negative	Total	
Status COVID-19 Ag/Flu A&B	Influenza A Positive	10	0	10	PPA: 100.0% 95% CI:72.3% to 100.0%
	Influenza A Negative	0	11	11	NPA: 100.0% 95% CI:74.1% to 100.0%
Total		10	11	21	

Status COVID-19 Ag/Flu A&B performance compared to *Status* Flu A&B: Influenza B

		Status Flu A&B: Influenza B			Performance (95%CI)
		Positive	Negative	Total	
Status COVID-19 Ag/Flu A&B	Influenza B Positive	11	0	11	PPA: 100.0% 95% CI: 74.1% to 100.0%
	Influenza B Negative	0	10	10	NPA: 100.0% 95% CI: 72.3% to 100.0%
Total		11	10	21	

The ***Status*™ COVID-19/Flu** test is a lateral flow immunoassay intended to aid in the rapid differential diagnosis of influenza A, B and COVID-19 viral infections. It is a modification of the test device used in the FDA-cleared Status Flu A&B and BioSign Flu A+B (K182157) to include monoclonal antibodies for the detection of SARS-CoV-2. Data for the detection of influenza A and B by the *Status* Flu A&B test are presented below

***Status* Flu A&B**

Prospective Clinical Study from 2007 to 2009

A prospective clinical study was conducted from January 2007 to March 2008 and during March and April 2009 to determine the performance of ***Status* Flu A&B** for nasopharyngeal swab specimens.

The samples were collected at 5 sites in the USA from patients who visited physicians' offices and clinics with signs and symptoms of respiratory infection during the study period. All collected samples were tested with ***Status* Flu A&B**, and were cultured. The culture was initially used as the comparator method. The samples that produced discrepant results between ***Status* Flu A&B** and viral culture were further analyzed with an FDA-cleared real time RT-PCR Flu A and B assay (PCR comparator assay hereafter).

The total number of patients tested was 862, of which 30% were 5 and younger, 38% were 6-21 years old, and the rest were older than 21. Forty-eight (48) percent were male and 52% were female. A total of 253 nasopharyngeal aspirate specimens and 609 nasopharyngeal swab or nasal swab specimens were included in the performance analyses below.

Nasopharyngeal/Nasal Swab Samples (combined): Comparison with Viral Culture

	Virus Culture Results			
Status Flu A+ B	Flu A Positive	Flu A Negative	Total	Performance
Flu A Positive	59	131*	190	Sensitivity: 90.8% 95% CI: 81.3-95.7%
Flu A Negative	6**	413	419	Specificity: 75.9% 95% CI: 72.2-79.3%
Total	65	544	609	

*Of 131 discrepant results, 107 were positive by both Status and the PCR comparator assay.
** Of 6 discrepant results, 1 was negative by both Status and the PCR comparator assay.

	Virus Culture Results			
Status Flu A+ B	Flu B Positive	Flu B Negative	Total	Performance
Flu B Positive	47	55*	102	Sensitivity: 85.5% 95% CI: 73.8-92.4%
Flu B Negative	8**	499	507	Specificity: 90.1% 95% CI: 87.3-92.3%
Total	55	554	609	

*Of 55 discrepant results, 27 were positive by both Status and the PCR comparator assay.
**Of 8 discrepant results, 3 were negative by both Status and the PCR comparator assay.

Subsequently all available remnant nasopharyngeal swab and nasal swab samples that produced concordant results between ***Status* Flu A&B** and viral culture (a subset of the concordant nasopharyngeal/nasal swab samples) were also further analyzed with the PCR comparator assay to supplement the PCR testing performed on discordant specimens. This subset of concordant samples between ***Status* Flu A&B** and viral culture includes 46% of all concordant positive samples and 33% of all concordant negative samples for the Flu A analyte, and 23% of all concordant positive samples and 31% of all concordant negative samples for the Flu B analyte.

Performance[3] of the ***Status* Flu A&B** against the PCR comparator assay for all nasopharyngeal and nasal swab samples are presented in the tables below.

Nasopharyngeal/Nasal Swab Samples (combined): Comparison with PCR

	PCR Results			
Status Flu A+ B	Flu A Positive	Flu A Negative	Total	Performance
Flu A Positive	165	25	190	Sensitivity: 92.2% 95% CI: 87.3-95.3%
Flu A Negative	14	405	419	Specificity: 94.2% 95% CI: 91.6-96.0%
Total	179	430	609	

	PCR Results			
Status Flu A+ B	Flu B Positive	Flu B Negative	Total	Performance
Flu B Positive	72	30	102	Sensitivity: 90.0% 95% CI: 81.5-94.8%
Flu B Negative	8	499	507	Specificity: 94.3% 95% CI: 92.0-96.0%
Total	80	529	609	

Prospective Clinical Study from 2014 to 2016

An additional prospective clinical study was conducted from December 2014 to May 2016 to evaluate the performance of ***Status* Flu A&B** for nasopharyngeal and nasal swab specimens when used by operators at CLIA-waived sites. The nasopharyngeal and nasal swab specimens were collected at 7 CLIA waived sites in the USA from patients with signs and symptoms of respiratory infection during the study period. All collected samples were tested with both the ***Status* Flu A&B** and the PCR comparator assay. The total number of patients tested prospectively in this clinical study was 307, of which 37% were 5 and younger, 50% were 6-21 years old, and the rest were older than 21. Forty-nine (49) percent were male and 51% were female.

The data showing the performance of the ***Status* Flu A&B** assay against the PCR comparator assay for all the prospectively collected and tested swab samples from 2014 to 2016 are presented in the tables below.

Nasopharyngeal/Nasal Swab Samples (combined): Comparison with PCR

	PCR Results			
Status Flu A+ B	Flu A Positive	Flu A Negative	Total	Performance
Flu A Positive	101	2	103	Sensitivity: 90.2 % 95% CI: 83.3-94.4%
Flu A Negative	11	193	204	Specificity: 99.0 % 95% CI: 96.3-99.7%
Total	112	195	307	

	PCR Results			
Status Flu A+ B	Flu B Positive	Flu B Negative	Total	Performance
Flu B Positive	27	3	30	Sensitivity: 81.8% 95% CI: 65.6-91.4%
Flu B Negative	6	271	277	Specificity: 98.9% 95% CI: 96.8-99.6%
Total	33	274	307	

Prospective Clinical Study from 2007 to 2009 and from 2014 to 2016

Combined prospective clinical data from the 2007 to 2009 study and the 2014 to 2016 CLIA waiver study against the PCR comparator assay are presented in the tables below.

Nasopharyngeal/Nasal Swab Samples (combined): Comparison with PCR

	PCR Results			
Status Flu A+ B	Flu A Positive	Flu A Negative	Total	Performance
Flu A Positive	266	27	293	Sensitivity: 91.4% 95% CI: 87.6-94.1%
Flu A Negative	25	598	623	Specificity: 95.7% 95% CI: 93.8-97.0%
Total	291	625	916	

	PCR Results			
Status Flu A+ B	Flu B Positive	Flu B Negative	Total	Performance
Flu B Positive	99	33	132	Sensitivity: 87.6% 95% CI: 80.3-92.5%
Flu B Negative	14	770	784	Specificity: 95.9% 95% CI: 94.3-97.1%
Total	113	803	916	

Analytical Performance

Limit of Detection (LOD)

Limit of detection (LOD) for SARS-CoV-2 and influenza A and B in the ***Status*™ COVID-19/Flu** was determined by evaluating different concentrations of heat inactivated viruses. Natural nasopharyngeal swab specimens were obtained from healthy donors and confirmed negative for COVID-19 and Influenza A&B using the ***Status*™ COVID-19/Flu** test. Negative natural nasopharyngeal swab specimens were eluted in PBS. Swab elutes were combined and mixed thoroughly to create a negative clinical matrix pool to be used as the diluent. The viruses were diluted in this natural nasopharyngeal swab matrix pool to generate virus dilutions for testing. Nasopharyngeal swab samples were prepared by adding 50µL of each virus dilution onto the sterile swab. The swab samples were tested according to the test procedure in package insert.

Virus Strains	Sources	LoD	#Positive/#Total	% Positive
SARS-COV-2 USA-WA1/2020	ATCC® Number, VR-1986HK™	2.7×10^3 $TCID_{50}$/mL	20/20	100
Influenza A Victoria/361/11(H3N2)	Zeptometrix, Cat# 0810240CF	4.51×10^1 $TCID_{50}$/mL	20/20	100
Influenza A A/California/07/2009(H1N1)	ATCC, Cat# VR-1894	2.08×10^5 $CEID_{50}$/mL	20/20	100
Influenza B Victoria/504/00	Zeptometrix, Cat# 0810571CF	5.64×10^2 $TCID_{50}$/mL	20/20	100
Influenza B Yamagata/16/88	Zeptometrix, Cat# 0810518CF	2.72×10^2 $TCID_{50}$/mL	20/20	100

Analytical Reactivity/ Inclusivity

The analytical reactivity of the monoclonal antibodies targeting SARS-CoV-2 in the ***Status*™ COVID-19/Flu** was evaluated with the currently available SARS-CoV-2 Strains.

2019-nCoV Strain/ Isolate	Source/Type	Analytical Reactivity
USA-WA1/2020	Zeptometrix Cat# 0810587CFHI/NR-52281	3.68 x10^3 $TCID_{50}$/mL
Hong Kong/VM20001061/2020	Zeptometrix Cat# 0810590CFHI/NR-52282	3.68 x10^3 $TCID_{50}$/mL
Italy-INMI1	Zeptometrix Cat# 0810589CFHI/NR-52284	6.52 x10^3 $TCID_{50}$/mL

The 2020 CDC Human Influenza Panel was tested with the ***Status*™ COVID-19/Flu** and ***Status* Flu A&B** tests**.** The panel was tested as per the swab protocol recommended by the CDC. Briefly, a series of 5-fold dilutions were prepared with each panel. These dilutions were tested with five replications until two consecutive dilutions were negative. Test results are tabulated below.

CDC human influenza virus A panel (VP2020) test result (Swab sample)

Influenza Virus (Type/Subtype)	Virus Strain Name	Virus Serial Dilution Concentration (EID_{50}/mL) and Number of Positive Results at Each Dilution (no. of positives /5 replicates)							
A(H3N2)	A/Perth/16/2009	Concentration	$10^{9.3}$	$2x10^{8.3}$	$4x10^{7.3}$	$8x10^{6.3}$	$1.6x10^{6.3}$	$3.2x10^{5.3}$	$6.4x10^{4.3}$
		BioSign Flu A&B	n/a	5/5	5/5	5/5	5/5	0/5	0/5
		tatus™ COVID-19/Flu	n/a	5/5	5/5	5/5	5/5	0/5	0/5
A(H3N2)	A/Hong Kong/2671/2019	Concentration	$10^{7.5}$	$2x10^{6.5}$	$4x10^{5.5}$	$8x10^{4.5}$	$1.6x10^{4.5}$	n/a	n/a
		BioSign Flu A&B	n/a	5/5	3/5	0/5	0/5	n/a	n/a
		tatus™ COVID-19/Flu	n/a	5/5	3/5	0/5	0/5	n/a	n/a
A(H1N1) pdm09	A/Christ Church /16/2010	Concentration	$10^{10.2}$	$2x10^{9.2}$	$4x10^{8.2}$	$8x10^{7.2}$	$1.6x10^{7.2}$	$3.2x10^{6.2}$	n/a
		BioSign Flu A&B	n/a	5/5	5/5	5/5	0/5	0/5	n/a
		tatus™ COVID-19/Flu	n/a	5/5	5/5	5/5	0/5	0/5	n/a
A(H1N1) pdm09	A/Guangdong-Maonan/1536/2019	Concentration	$10^{9.1}$	$2x10^{8.1}$	$4x10^{7.1}$	$8x10^{6.1}$	$1.6x\ 10^{6.1}$	$3.2x10^{5.1}$	n/a
		BioSign Flu A&B	n/a	5/5	5/5	1/5	0/5	0/5	n/a
		tatus™ COVID-19/Flu	n/a	5/5	5/5	2/5	0/5	0/5	n/a

CDC human influenza virus B panel (VP2020) test result (Swab sample)

Influenza Virus (Type/Subtype)	Virus Strain Name	Virus Serial Dilution Concentration (EID50/mL) and Number of Positive Results at Each Dilution (no. of positives /5 replicates)							
B (Victoria lineage)	B/Michigan/09/2011	Concentration	$10^{6.9}$	$2x10^{5.9}$	$4x10^{4.9}$	$8x10^{3.9}$	$1.6x10^{3.9}$	n/a	n/a
		BioSign Flu A&B	n/a	5/5	5/5	0/5	0/5	n/a	n/a
		Status™ COVID-19/Flu	n/a	5/5	5/5	0/5	0/5	n/a	n/a
B (Victoria lineage)	B/Washington/02/2019	Concentration	$10^{9.2}$	$2x10^{8.2}$	$4x10^{7.2}$	$8x10^{6.2}$	$1.6x 10^{6.2}$	$3.2x10^{5.2}$	n/a
		BioSign Flu A&B	n/a	5/5	5/5	5/5	0/5	0/5	n/a
		Status™ COVID-19/Flu	n/a	5/5	5/5	5/5	0/5	0/5	n/a
B (Yamagata lineage)	B/Texas/81/2016	Concentration	$10^{8.3}$	$2x10^{7.3}$	$4x10^{6.3}$	$8x10^{5.3}$	$1.6x10^{5.3}$	$3.2x10^{4.3}$	$6.4x10^{3.3}$
		BioSign Flu A&B	n/a	5/5	5/5	5/5	5/5	0/5	0/5
		Status™ COVID-19/Flu	n/a	5/5	5/5	5/5	5/5	0/5	0/5
B (Yamagata lineage)	B/Phuket/3073/2013	Concentration	$10^{9.9}$	$2x10^{8.9}$	$4x10^{7.9}$	$8x10^{6.9}$	$1.6x10^{6.9}$	$3.2x10^{5.9}$	n/a
		BioSign Flu A&B	n/a	5/5	5/5	3/5	0/5	0/5	n/a
		Status™ COVID-19/Flu	n/a	5/5	5/5	4/5	0/5	0/5	n/a

The analytical inclusivity for influenza A and B was demonstrated with ***Status* Flu A&B** using a total of 49 influenza strains: 34 strains of influenza A type and 15 strains of influenza B type. Additional information detailing this testing can be found in ***Status* Flu A&B** package insert.

Analytical Specificity (Cross-reactivity)

The analytical Specificity (Cross-reactivity) was established for normal or pathogenic flora that is reasonably likely to be encountered in clinical specimens. The results are shown in the tables below.

Cross-Reactivity-SARS-CoV-2

Potential Cross-reactant	Concentration
Human coronavirus 229E	1.0×10^5 $TCID_{50}$/mL
Human coronavirus OC43	1.0×10^5 $TCID_{50}$/mL
Human coronavirus NL63	1.0×10^5 $TCID_{50}$/mL
Adenovirus C1	1.0×10^5 $TCID_{50}$/mL
Human Metapneumovirus(hMPV)	3.89×10^4 $TCID_{50}$/mL
Parainfluenza virus 1, C35	1.0×10^5 $TCID_{50}$/mL
Parainfluenza virus 2, Greer	1.0×10^5 $TCID_{50}$/mL
Parainfluenza virus 3, C243	1.0×10^5 $TCID_{50}$/mL
Parainfluenza virus 4, CH19503	1.0×10^5 $TCID_{50}$/mL
Influenza A A/California/2/2014(H3N2)	1.0×10^5 $TCID_{50}$/mL
Influenza A A/Hong Kong/8/68(H3N2)	1.0×10^5 $TCID_{50}$/mL
Influenza A A/California/07/2009(H1N1)	1.0×10^5 $CEID_{50}$/mL
Influenza B B/Russia/69	1.0×10^5 $CEID_{50}$/mL
Influenza B B/Florida/02/06	1.0×10^5 $TCID_{50}$/mL
Human enterovirus 71Strain: H	1.0×10^5 $TCID_{50}$/mL
Human respiratory syncytial virus, A2	1.0×10^5 PFU/mL
Rhinovirus 2060	1.0×10^5 PFU/mL
Haemophilus influenza	4×10^4 cfu/mL
Streptococcus pneumoniae	2.0×10^4 cfu/mL
Streptococcus pyogenes, Bruno	4.0×10^6 cfu/mL
Candida albicans	1.0×10^6 cfu/mL
Bordetella pertussis, 18323	1.0×10^6 cfu/mL
Mycoplasma pneumoniae	1.0×10^6 cfu/mL
Chlamydia pneumoniae TW-183	1.0×10^6 IFU/mL
Legionella pneumophila	1.0×10^6 cfu/mL
Pneumocystis jirovecii	1.0×10^6 cfu/mL
Staphylococcus epidermidis	1.0×10^6 cfu/mL
Staphylococcus aureus	1.0×10^6 cfu/mL

Cross-Reactivity-Influenza A

Potential Cross-reactant	Concentration
Human corona virus 229E	1.0×10^5 $TCID_{50}$/mL
Human corona virus OC43	1.0×10^5 $TCID_{50}$/mL

Human corona virus NL63	1.0 x 10^5 $TCID_{50}$/mL
Adenovirus C1	1.0 x 10^5 $TCID_{50}$/mL
Human Metapneumovirus(hMPV)	3.89 x 10^4 $TCID_{50}$/mL
Parainfluenza virus 1, C35	1.0 x 10^5 $TCID_{50}$/mL
Parainfluenza virus 2, Greer	1.0 x 10^5 $TCID_{50}$/mL
Parainfluenza virus 3, C243	1.0 x 10^5 $TCID_{50}$/mL
Parainfluenza virus 4, CH19503	1.0 x 10^5 $TCID_{50}$/mL
Influenza B B/Russia/69	1.0 x 10^5 $CEID_{50}$/mL
Influenza B B/Florida/02/06	1.0 x 10^5 $TCID_{50}$/mL
Human enterovirus 71Strain: H	1.0 x 10^5 $TCID_{50}$/mL
Human respiratory syncytial virus, A2	1.0 x 10^5 PFU/mL
Rhinovirus 2060	1.0 x 10^5 PFU/mL
Haemophilus influenza	4 x 10^4 cfu/mL
Streptococcus pneumoniae	2.0 x 10^4 cfu/mL
Streptococcus pyogenes, Bruno	4.0 x 10^6 cfu/mL
Candida albicans	1.0 x 10^6 cfu/mL
Bordetella pertussis, 18323	1.0 x 10^6 cfu/mL
Mycoplasma pneumoniae	1.0 x 10^6 cfu/mL
Chlamydia pneumoniae TW-183	1.0 x 10^6 IFU/mL
Legionella pneumophila	1.0 x 10^6 cfu/mL
Pneumocystis jirovecii	1.0 x 10^6 cfu/mL
Staphylococcus epidermidis	1.0 x 10^6 cfu/mL
Staphylococcus aureus	1.0 x 10^6 cfu/mL

Cross-Reactivity- Influenza B

Potential Cross-reactant	Concentration
Human corona virus 229E	1.0 x 10^5 $TCID_{50}$/mL
Human corona virus OC43	1.0 x 10^5 $TCID_{50}$/mL
Human corona virus NL63	1.0 x 10^5 $TCID_{50}$/mL
Adenovirus C1	1.0 x 10^5 $TCID_{50}$/mL
Human Metapneumovirus(hMPV)	3.89 x 10^4 $TCID_{50}$/mL
Parainfluenza virus 1, C35	1.0 x 10^5 $TCID_{50}$/mL
Parainfluenza virus 2, Greer	1.0 x 10^5 $TCID_{50}$/mL
Parainfluenza virus 3, C243	1.0 x 10^5 $TCID_{50}$/mL
Parainfluenza virus 4, CH19503	1.0 x 10^5 $TCID_{50}$/mL
Influenza A A/California/2/2014(H3N2)	1.0 x 10^5 $TCID_{50}$/mL
Influenza A A/Hong Kong/8/68(H3N2)	1.0 x 10^5 $TCID_{50}$/mL
Influenza A A/California/07/2009(H1N1)	1.0 x 10^5 $CEID_{50}$/mL
Human enterovirus 71Strain: H	1.0 x 10^5 $TCID_{50}$/mL
Human respiratory syncytial virus, A2	1.0 x 10^5 PFU/mL
Rhinovirus 2060	1.0 x 10^5 PFU/mL
Haemophilus influenza	4 x 10^4 cfu/mL

Streptococcus pneumoniae	2.0 x 10^4 cfu/mL
Streptococcus pyogenes, Bruno	4.0 x 10^6 cfu/mL
Candida albicans	1.0 x 10^6 cfu/mL
Bordetella pertussis, 18323	1.0 x 10^6 cfu/mL
Mycoplasma pneumoniae	1.0 x 10^6 cfu/mL
Chlamydia pneumoniae TW-183	1.0 x 10^6 IFU/mL
Legionella pneumophila	1.0 x 10^6 cfu/mL
Pneumocystis jirovecii	1.0 x 10^6 cfu/mL
Staphylococcus epidermidis	1.0 x 10^6 cfu/mL
Staphylococcus aureus	1.0 x 10^6 cfu/mL

To estimate the likelihood of cross-reactivity with SARS-CoV-2, Influenza A or B virus in the presence of organisms that were not available for wet testing, due to unavailability of BSL-3 access, *in silico* analysis using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) was used to assess the degree of protein sequence homology.

- The comparison between SARS-CoV-2 nucleocapsid protein, MERS-CoV and *human corona virus* HKU1 revealed that cross-reactivity cannot be ruled out. Homology for HKU1 and MERS-CoV is relatively low, at 48.5% across 91% of sequence and 36.7% across 82% of the sequence, respectively.
- Wet testing with SARS-coronavirus was not conducted, however, in silico analysis indicated that cross-reactivity is likely.
- No significant similarity found between *Mycobacterium tuberculosis*, and SARS-CoV-2, or between *Mycobacterium tuberculosis* and Influenza A or B, thus homology based cross-reactivity can be ruled out.
- No significant similarity found between *SARS-Coronavirus* and Influenza A or B, thus homology based cross-reactivity can be ruled out.
- No significant similarity found between *MERS-coronavirus* and Influenza A or B, thus homology based cross-reactivity can be ruled out.
- No significant similarity found between *Human coronavirus HKU* and Influenza A or B, thus homology based cross-reactivity can be ruled out.

Endogenous Interfering Substances

The potential interference of endogenous substances with the antibodies used for the detection of COVID-19, Influenza A and B was examined by testing nineteen (19) substances in a negative clinical matrix, in the absence or presence of each virus; at 3 x LOD concentrations for SARS-CoV-2, Influenza A, and Influenza B. The interference study was conducted using medically relevant concentrations of the potentially interfering substances listed below to assess the potential interference of the substances on the performance of the ***Status*™ COVID-19/Flu** test.

Interfering substance	Active Ingredient	Concentration
Mucin	Mucin	5.0 mg/mL
Whole blood (human)	Blood	5%
Halls Cough Suppressant/Oral Anesthetic Drops	Menthol	1.5 mg/mL
Nasacort Allergy 24H	Triamcinolone acetonide	5%
Rhinocort Allergy Spray	Budesonide (Glucocorticoid)	5%
ZICAM Cold Remedy + Multi-Symptom Relief	Galphimia glauca, luffa operculata, sabadilla	5%
Afrin Nasal Spray	Oxymetazoline HCL	15%
Cepacol Extra Strength	Benzocaine, Menthol	1.5 mg/mL
Flonase Allergy Relief	Fluticasone Propionate (Glucocorticoid)	5%
Oseltamivir	Oseltamivir	5 mg/mL
Saline nasal spray	Saline	15%
NasoGEL(NeilMed)	Sodium Chloride, Sodium Bicarbonate, Sodium Hyaluronate	5%
Tobramycine	Tobramycin	10 µg/mL
Zanamivir	Zanamivir	282.0 ng/mL
CVS Sinus Relief Nasal spray	Phenylephrine hydrochloride	15%
NasalCrom Nasal spray	Cromolyn sodium	15%
Sore throat phenol spray	Phenol	15%
Homeopathic (Alkalol)	Galphima glauca 6X, Luffa operculata 6X, Sabadila 6X	1:10 dilution
Mupirocin	Mupirocin	10mg/mL

High-dose Hook Effect

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

Virus Type	Viral Strain	Highest Concentration tested
SARS-CoV-2	USA-WA1/2020	1.15×10^7 $TCID_{50}$/mL
Influenza A (H3N2)	A/California/2/2014	5.8×10^5 $TCID_{50}$/mL
Influenza A(H3N2)	A/Hong Kong/8/68	1.26×10^6 $TCID_{50}$/mL
Influenza A (H3N2)	Victoria/361/11	1.41×10^5 $TCID_{50}$/mL
Influenza A (H1N1)	A/California/07/2009	5.2×10^7 $CEID_{50}$/mL
Influenza B	B/Russia/69	1.5×10^6 $CEID_{50}$/mL
Influenza B	B/Florida/02/06	1.05×10^6 $TCID_{50}$/mL
Influenza B	B/Victoria/504/00	$1.41 \times 10^5 TCID_{50}$/mL
Influenza B	B/Yamagata/16/88	1.70×10^5 $TCID_{50}$/mL

Co-infection (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 as well as near LOD influenza A and influenza B in the presence of

high levels of SARS-CoV-2. No competitive interference was seen between SARS-CoV-2 and Influenza A and B in this testing at the concentration listed in the table below.

Co-infection: SARS-CoV-2 vs. Influenza A

Competitive virus	Concentration	Competitive target virus	Concentration	Competitive Target percent Positivity
Influenza A (H3N2) A/California/2/2014	1.0×10^5 $TCID_{50}$/mL	SARS-CoV-2 USA-WA1/2020	4.0×10^3 $TCID_{50}$/mL	100%
Influenza A A/Hong Kong/8/68(H3N2)	1.0×10^5 $TCID_{50}$/mL	SARS-CoV-2 USA-WA1/2020	4.0×10^3 $TCID_{50}$/mL	100%
Influenza A (H3N2) Victoria/361/11	1.0×10^5 $TCID_{50}$/mL	SARS-CoV-2 USA-WA1/2020	4.0×10^3 $TCID_{50}$/mL	100%
Influenza A (H1N1) A/California/07/2009	1.0×10^6 $CEID_{50}$/mL	SARS-CoV-2 USA-WA1/2020	4.0×10^3 $TCID_{50}$/mL	100%
SARS-CoV-2 USA-WA1/2020	1.0×10^5 $TCID_{50}$/mL	Influenza A (H3N2) Victoria/361/11	6.5×10^1 $TCID_{50}$/mL	100%
SARS-CoV-2 USA-WA1/2020	1.0×10^5 $TCID_{50}$/mL	Influenza A (H1N1) A/California/07/2009	3.0×10^5 $CEID_{50}$/mL	100%

Co-infection: SARS-CoV-2 vs. Influenza B

Competitive virus	Concentration	Competitive target virus	Concentration	Competitive Target percent Positivity
Influenza B B/Russia/69	1.0×10^5 $CEID_{50}$/mL	SARS-CoV-2 USA-WA1/2020	4.0×10^3 $TCID_{50}$/mL	100%
Influenza B B/Florida/02/06	1.0×10^5 $TCID_{50}$/mL	SARS-CoV-2 USA-WA1/2020	4.0×10^3 $TCID_{50}$/mL	100%
Influenza B Victoria/504/00	1.0×10^5 $TCID_{50}$/mL	SARS-CoV-2 USA-WA1/2020	4.0×10^3 $TCID_{50}$/mL	100%
Influenza B Yamagata/16/88	1.0×10^5 $TCID_{50}$/mL	SARS-CoV-2 USA-WA1/2020	4.0×10^3 $TCID_{50}$/mL	100%
SARS-CoV-2 USA-WA1/2020	1.0×10^5 $TCID_{50}$/mL	Influenza B Victoria/504/00	8.0×10^2 $TCID_{50}$/mL	100%
SARS-CoV-2 USA-WA1/2020	1.0×10^5 $TCID_{50}$/mL	Influenza B Yamagata/16/88	4.0×10^2 $TCID_{50}$/mL	100%

Assistance

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

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