CLSI PROCEDURE

Product Name: ***Status*** **™ COVID-19/Flu**
Item Number: 33225

Institution:	
Prepared By:	Date:
Title:	

Accepted By:	Date:
Title:	

Accepted By:		Date:	

Discontinued By	Date:

lifeSign

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SECTION 1 - TEST NAME

***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

SECTION 2 - INTENDED USAGE

***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.

SECTION 3 - 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.

SECTION 4 - 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*™ COVID19/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 SARSCoV-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 SARSCoV-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 Product Name: Page 6 of 28 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 AND STORAGE

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 Instructions (1)

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. **DO NOT** open foil pouch until ready to use test.

SECTION 6 - MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Latex Gloves

SECTION 7 - WARNINGS AND PRECAUTIONS

- 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. Product Name: Page 7 of 28
- 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.

SECTION 8 - PATIENT PREPARATIONS AND SPECIMEN COLLECTION

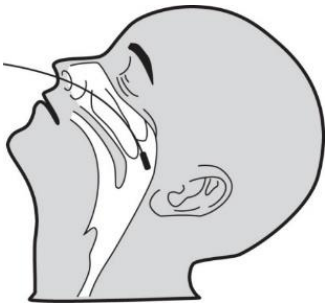
- Inadequate or inappropriate specimen collection, storage, and transport are likely to yield false negative test results. Training in specimen collection is highly recommended because of the importance of specimen quality.
- To collect nasopharyngeal specimens, only the swab provided in the ***Status*™ 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. Product Name: Page 8 of 28
- 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.



SECTION 9 - QUALITY CONTROL AND ASSURANCE

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*™ COVID19/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.

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.

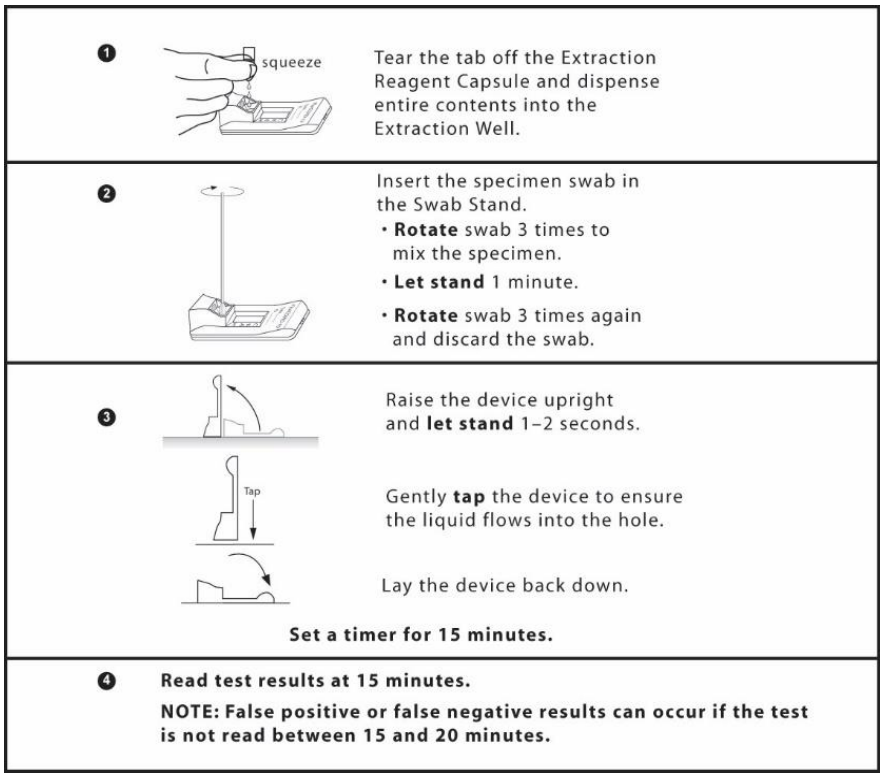
4. Read results at 15 minutes. Results should not be read after 20 minutes.

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.



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.

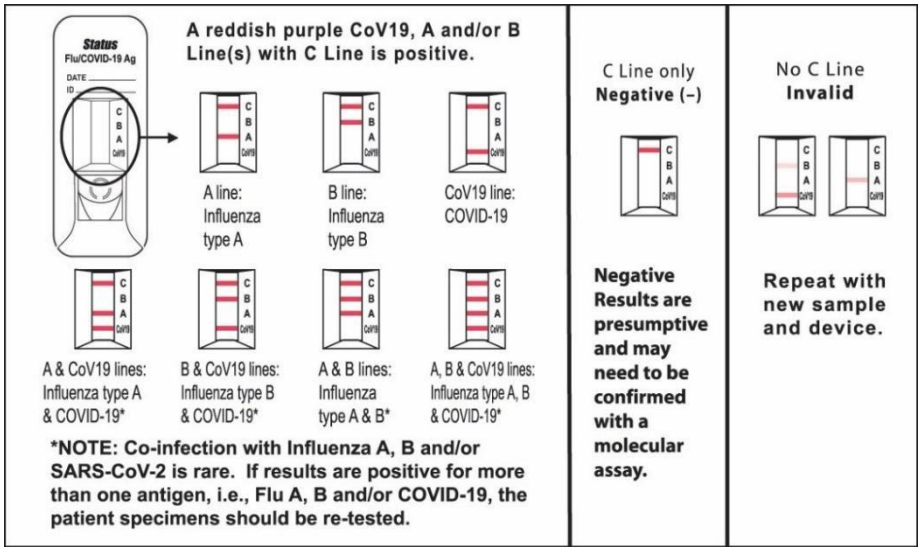
Note: The Test line (reddish purple line) may vary in shade and intensity (light or dark, weak or strong) depending on the concentration of antigen detected. The intensity of the Control line should not be compared to that of the Test line for the interpretation of the test result. Even a light or faint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

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

- 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.

SECTION 13 – CLINICAL PERFORMANCE

A prospective study was performed in which with one hundred twenty five (125) direct nasopharyngeal swabs were sequentially enrolled 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 (SARSCoV-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/Flu** 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/Flu** performance compared to Status Flu A&B: Influenza A

		Status Flu A&B: Influenza A			Performance (95% CI)
		Positive	Negative	Total	
Status™ COVID-19/Flu	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/Flu** performance compared to Status Flu A&B: Influenza B

		Status Flu A&B: Influenza B			Performance (95% CI)
		Positive	Negative	Total	
Status™ COVID-19 /Flu	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	

SECTION 14 – 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.

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	$10^{9.3}$	2x$10^{8.3}$	4x$10^{7.3}$	8x$10^{6.3}$	1.6x$10^{6.3}$	3.2x$10^{5.3}$	6.4x$10^{4.3}$
		BioSign Flu A&B	n/a	5/5	5/5	5/5	5/5	0/5	0/5
		Status™ COVID-	n/a	5/5	5/5	5/5	5/5	0/5	0/5

		19/Flu							
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
		Status™ 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
		Status™ 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	$10^{9.1}$	$2x10^{8.1}$	$4x10^{7.1}$	$8x10^{6.1}$	$.6x\ 10^{6.1}$	$3.2x10^{5.1}$	n/a
		BioSign Flu A&B	n/a	5/5	5/5	1/5	0/5	0/5	n/a
		Status™ 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 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 A

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 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	1.0×10^5 $TCID_{50}$/mL
Human corona virus OC43	1.0×10^5 $TCID_{50}$/mL
Human corona virus 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
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

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 x 10^5 $CEID_{50}$/mL	SARS-CoV-2 USA-WA1/2020	4.0 x 10^3 $TCID_{50}$/mL	100%
Influenza B B/Florida/02/06	1.0 x 10^5 $TCID_{50}$/mL	SARS-CoV-2 USA-WA1/2020	4.0 x 10^3 $TCID_{50}$/mL	100%
Influenza B Victoria/504/00	1.0 x 10^5 $TCID_{50}$/mL	SARS-CoV-2 USA-WA1/2020	4.0 x 10^3 $TCID_{50}$/mL	100%
Influenza B Yamagata/16/88	1.0 x 10^5 $TCID_{50}$/mL	SARS-CoV-2 USA-WA1/2020	4.0 x 10^3 $TCID_{50}$/mL	100%
SARS-CoV-2 USA-WA1/2020	1.0 x 10^5 $TCID_{50}$/mL	Influenza B Victoria/504/00	8.0 x 10^2 $TCID_{50}$/mL	100%
SARS-CoV-2 USA-WA1/2020	1.0 x 10^5 $TCID_{50}$/mL	Influenza B Yamagata/16/88	4.0 x 10^2 $TCID_{50}$/mL	100%

SECTION 15 - REFERENCES

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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: technical@lifesignmed.com, or via phone at 800-526-2125 or 732-246-3366)

lifeSign

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

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 Samples				
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: _____

FACT SHEET FOR HEALTHCARE PROVIDERS

Princeton BioMeditech Corp.

***Status*™ COVID-19/Flu**

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the *Status*™ COVID-19/ Flu rapid test.

Status™ COVID-19/Flu is authorized for use with certain respiratory specimens collected from individuals who are suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider within the first five days of the onset of symptoms.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: Princeton BioMeditech Corp. - *Status*™ COVID-19/Flu Test.

What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed

fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea) although some individuals experience only mild symptoms or no symptoms at all. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgia, headache, sore throat or new loss of taste or smell, nausea or vomiting or diarrhea.

Signs and symptoms may appear any time from 2 to 14 days after exposure to the virus, and the median time to symptom onset is approximately 5 days. For further information on the symptoms of COVID-19 please see the link provided in *"Where can I go for updates and more information?"* section.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States. Please check the CDC COVID-19 webpage (see link provided in *"Where can I go for updates and more information?"* section at the end of this document) or your local jurisdictions website for the most up to date information.

What are the signs and symptoms of influenza?

The signs and symptoms of influenza usually develop suddenly and are similar to those of COVID-19. Common signs and symptoms of influenza are fever, cough, sore throat, runny/stuffy nose, body aches, headaches, and fatigue.

What do I need to know about COVID-19 testing?

Current information on COVID-19 for healthcare providers is avail- able at CDC's webpage, *Information for Healthcare Professionals* (see links provided in *"Where can I go for updates and more information?"* section).

- *Status*™ COVID-19/Flu can be used to test in direct naso- pharyngeal (NP) swab specimens.
- *Status*™ COVID-19/Flu should be ordered for the qualitative detection and differentiation of the nucleocapsid protein

This test is to be performed only using certain respiratory specimens collected from individuals suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider within the first five days of the onset of symptoms

antigens from SARS-CoV-2, influenza A and influenza B in direct nasopharyngeal (NP) swab specimens from individ- uals suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider within the first five days of the onset of symptoms.

- *Status*™ COVID-19/Flu is authorized for use in laborato- ries certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high, moderate or waived com- plexity tests.
- *Status*™ COVID-19/Flu is authorized for use at Point of Care (POC), i.e., in patient care settings operating under CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Specimens should be collected with appropriate infection control precautions. Current guidance is available at the CDC's website (see links provided in *"Where can I go for updates and more information?"* section).

When collecting and handling specimens from individuals sus- pected of being infected with COVID-19, appropriate personal protective equipment should be used as outlined in the CDC *Interim Laboratory Biosafety Guidelines for Handling and Pro- cessing Specimens Associated with Coronavirus Disease 2019 (COVID-19). For additional information, refer to CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Speci- mens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19)* (see links provided in *"Where can I go for updates and more information?"* section).

What does it mean if the specimen tests positive for the virus that causes COVID-19?
A positive test result for COVID-19 indicates that antigens from SARS-CoV-2 was detected, and therefore the patient is infected with the virus and presumed to be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiological data (such as local prevalence rates and current outbreak/epicenter locations) in making a final diagnosis and patient management decisions. Patient management should be made by a healthcare provider and follow current CDC guidelines.

Status™ COVID-19/Flu has been designed to minimize the likelihood of false positive test results. In the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19 patients, limits in the ability to work, delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

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

What does it mean if the specimen tests negative for the virus that causes COVID-19?
A negative test result for this test means that SARS-CoV-2 antigens were not present in the specimen above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

Antigen tests are known to be less sensitive than molecular tests that detect viral nucleic acids. The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 5 of illness may be more likely to be negative compared to a RT-PCR assay. Therefore, negative results, from patients with symptom onset beyond five days, should be treated as presumptive and confirmation with a molecular assay, if nec- essary, for patient management, may be performed. It is possible to test a person too early or too late during COVID-19 infection to make an accurate diagnosis via *Status*™ COVID-19/Flu.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of a pa- tient's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that COVID-19

is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If COVID-19 is still suspected based on exposure history together with other clinical findings,

re-testing or testing with molecular methods should be considered by healthcare providers in consultation with public health author- ities. Additional testing may be helpful to ensure testing was not conducted too early.

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

A negative antigen test should not be the sole basis used to determine if a patient can end isolation precautions. For additional recommendations regarding infection control, refer to

CDC's *Discontinuation of Isolation for Persons with COVID-19 Not in Healthcare Settings* (Interim Guidance) (see links provided in *"Where can I go for updates and more information"* section).

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

What does it mean if the specimen tests positive for influenza A and/or B viruses?
A positive test result for influenza A virus or influenza B virus indicates that proteins from one or both of these viruses was detected, the patient is infected with the virus(es) and is presumed to be contagious. Laboratory test results should always be considered in the context of clinical findings and observations and epidemiological data in making a final diagnosis. Patient management decisions should be made by a healthcare provider and follow current CDC guidelines.

Status™ COVID-19/Flu has been designed to minimize the like- lihood of false-positive test results. However, in the event of a false-positive result, risks to individuals could include the follow- ing: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family of friends, limits in the ability to work, delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of an antiviral medication or other therapy, or other unintended adverse effects.

What does it mean if the specimen tests negative for influen- za viruses?
A negative test result for influenza viruses means that influenza A and/or B proteins were not present in the specimen

above the limit of detection. However, a negative result does not rule out influenza virus infection and should not be used as the sole basis for treatment or patient management decisions.

When diagnostic testing results are negative, the possibility of a false-negative result should be considered in the context of a

patient's recent exposures and the presence of clinical signs and symptoms consistent with influenza. The possibility of a false negative result should especially be considered if the patient's recent

exposures or clinical presentation indicate that influenza is likely, and diagnostic test results for other causes of illness (e.g., other respiratory illness) are negative. If influenza is still suspected based on exposure history and clinical findings,

re-testing should be considered by healthcare providers in consultation with public health authorities.

Risks to an individual from a false-negative *Status*™ COVID-19/Flu result for influenza A or B include: delayed or lack of supportive treatment; lack of monitoring of infected patients and their household or other close contacts for symptoms, resulting in increased risk of spread of influenza within the community; or other unintended adverse events. Risks to an asymptomatic patient from a false-negative *Status*™ COVID-19/Flu result for influenza A or B include: lack of monitoring of infected patients and their household or other close contacts for symptoms, resulting in increased risk of spread of influenza within the community; or other unintended adverse events.

Laboratory test results should always be considered in the context of clinical findings and observations and/or epidemiological data in making a final diagnosis. Patient management decisions should be made by a healthcare provider and follow current CDC guidelines.

What does it mean if the specimen tests positive for SARS- CoV-2 and one or both influenza (A and/or B) viruses? Is co-infection possible?

Yes, it is possible for an individual to be infected with influenza A virus, influenza B virus, and/or SARS-CoV-2 simultaneously. A positive test result for the viruses that cause

COVID-19 and influenza A and/or B indicates that antigens from these viruses were detected, the patient may be co-infected, and is presumed to be contagious. Laboratory test results should always be considered in the context of clinical findings and ob- servations and epidemiological data in making a final diagnosis. Patient management decisions should be made with a healthcare provider and follow current CDC guidelines.

What is an EUA?

The United States FDA has made this test available under an emergency access mechanism called an Emergency Use Autho- rization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19. An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is rea- sonable to believe that this IVD may be effective in diagnosing COVID-19.

The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used).

What are the approved available alternatives?
There are no approved available alternative tests. FDA has issued EUAs for other tests that can be found at: https://www.fda.gov/emergency-preparedness-and-response/ mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

Where can I go for updates and more information? CDC webpages:
General: https://www.cdc.gov/COVID19

Symptoms:

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

Healthcare Professionals: https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html
Information for Laboratories: https://www.cdc.gov/coronavi- rus/2019-nCoV/guidance-laboratories.html

Laboratory Biosafety: https://www.cdc.gov/coronavi- rus/2019-nCoV/lab-biosafety-guidelines.html Isolation Precautions in Healthcare Settings: https://www.cdc.gov/coronavirus/2019-ncov/infection-con- trol/control-recommendations.html
Specimen Collection: https://www.cdc.gov/coronavi- rus/2019-nCoV/guidelines-clinical-specimens.html Infection Control: https://www.cdc.gov/coronavi- rus/2019-ncov/infection-control/index.html
Discontinuation of Isolation: https://www.cdc.gov/coronavi- rus/2019-ncov/hcp/disposition-in-home-patients.html Influenza: https://www.cdc.gov/flu/index.htm

FDA webpages:
General: www.fda.gov/novelcoronavirus
EUAs: (includes links to patient fact sheet and manufac- turer's instructions)
https://www.fda.gov/medical-devices/ coronavirus-disease-2019-covid-19-emergency-use-autho-rizations-medical-devices/vitro-diagnostics-euas

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FACT SHEET FOR PATIENTS

Princeton BioMeditech Corp.

***Status*™ COVID-19/Flu**

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using *Status*™ COVID-19/Flu.

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

For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage: https://www.cdc.gov/COVID19

For the most up to date information on Influenza, please visit the CDC Influenza webpage: https://www.cdc.gov/flu

What is COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS- CoV-2 virus can be spread to others not just while one is sick, but even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link: https://www.cdc.gov/coronavirus/2019-ncov/ symptoms-testing/symptoms.html.

What is Influenza?

Influenza (flu) is a contagious respiratory illness caused by influenza viruses. Influenza viruses can cause mild to severe illness. Serious outcomes of the flu can result in hospitalization or death. Some people, such as older people, young children, and people with certain underlying health conditions, are at higher risk for serious flu complications. There are two main types of influenza viruses: types A and B. Both type A and B influenza viruses regularly spread in people, and are responsible for seasonal flu each year.

Influenza viruses can be spread to others before and after a person shows signs and symptoms of being sick.

What is the *Status*™ COVID-19/Flu?

The test is designed to simultaneously detect three types of viruses: two types that cause influenza (type A and type B) and the virus that causes COVID-19 (SARS-CoV-2) in nasopharyngeal swabs.

Why was my sample tested?

You were tested because your healthcare provider believes you may have been exposed to the virus that causes COVID-19 based on your signs and symptoms (e.g., fever, cough, difficulty breathing), and/or other risk factors and you are within the first five days of the onset of symptoms.

What are the known and potential risks and benefits of the test?
Potential risks include:

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

Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19, influenza A or influenza B to your family and others in your community

What does it mean if I have a positive test result for SARS- CoV-2?

If you have a positive test result, it is very likely that you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. You should follow CDC guidance to reduce the potential transmission of disease.

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

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

What does it mean if I have a positive test result for SARS-CoV-2 and influenza (A and/or B) viruses?
It is possible for an individual to be infected with influenza A virus, influenza B virus, and/or SARS-CoV-2 virus at the same time. Your healthcare provider will work with you to determine how best to care for you based on these test results, your medical history, and your symptoms.

What does it mean if I have a negative test result for SARS-CoV-2, influenza (A and/or B) viruses?
A negative test result means that proteins from the virus that causes COVID-19 or influenza were not found in your sample.

However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19 or influenza. You might test negative if the sample was collected early during your infection. You could also be exposed to COVID-19 after your sample was collected and then have become infected.

This means that you could possibly still have COVID-19 or influenza even though the test result is negative. If your test is negative, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you. The amount of antigen in a sample may decrease the longer you have symptoms of infection. Specimens may be more likely to be negative compared to a molecular assay for SARS-CoV-2 or influenza.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

What are the differences between antigen tests and other COVID-19 tests?
There are different kinds of tests for diagnosing COVID-19. Molecular tests (also known as PCR tests) detect genetic material from the virus. Antigen tests detect proteins from the virus. Antigen tests are very specific for the virus, but are not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection.

If your test result is negative, you should discuss with your healthcare provider whether an additional molecular test would help with your care, and when you should discontinue home isolation. If you do not have an additional test to determine if you are infected and may spread the infection to others, the CDC currently recommends that you should stay home until three things have happened:

- You have had no fever for at least 24 hours (that is one full days of no fever without the use of medicine that reduces fevers)
  AND
- Other symptoms have improved (for example, when your cough or shortness of breath has improved) AND
- At least 10 days have passed since your symptoms first appeared.

For more information, the CDC has provided guidelines on how to prevent the spread of COVID-19 if you are sick: https://www.cdc.gov/coronavirus/2019-ncov/downloads/ sick-with-2019-nCoV-fact-sheet.pdf.

Is this test FDA-approved or cleared?
No. This test is not yet approved or cleared by the United States FDA. When there are no FDA-approved or cleared tests available, and other criteria are met, FDA can make tests available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA for this test is supported by the Secretary of Health and Human Services (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics for the detection and/or diagnosis of the virus that causes

COVID-19. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying emergency of IVDs, unless it is terminated or revoked by FDA (after which the test may no longer be used).

What are the approved alternatives?
There are approved influenza tests, but there is not yet an approved available alternative test for influenza combined with COVID-19 in one test. FDA has issued EUAs for other tests that can be found at:

https://www.fda.gov/emergency-preparedness-and-re- sponse/mcm-legal-regulatory-and-policy-framework/emer- gency-use-authorization.

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Where can I go for updates and more information? The most up-to-date information on COVID-19 is available at the CDC General Webpage: https://www.cdc.gov/COVID19. In addition, please also contact your healthcare provider with any questions/concerns.