

Status™ COVID-19/Flu A&B

Rapid Immunoassay for Direct Detection and

Differential Diagnosis of SARS-CoV-2, Influenza Type A, and Type B Antigens

For *In Vitro* Diagnostic Use

For Rx Use Only

For use under an Emergency Use Authorization only

Catalog No. 33225

Intended Use

Status™ COVID-19/Flu A&B test is a lateral flow immunoassay intended for the *in vitro* rapid, simultaneous qualitative detection and differentiation of nucleocapsid protein antigen from SARS-CoV-2, influenza A and/or influenza B directly from nasopharyngeal or anterior nasal swab specimens collected from individuals, who are suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider- within the first five (5) days of symptom onset when tested at least twice over three days with at least 48 hours between tests. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high, or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

The **Status™ COVID-19/Flu A&B** does not differentiate between SARS-CoV or SARS-CoV-2 viruses.

Results are for the simultaneous *in vitro* detection and differentiation of nucleocapsid protein antigens of SARS-CoV-2, influenza A and influenza B, and is not intended to detect influenza C antigens. These viral antigens are generally detectable in nasopharyngeal or anterior nasal 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 definitive 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.

All negative SARS-CoV-2 results are 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 measures such as isolating from others and wearing masks. 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.

All negative influenza A and B test results are 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.

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 A&B** is intended for use by medical professionals or trained operators who are proficient in performing tests in point of care settings.

The **Status™ COVID-19/Flu A&B** test is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

Summary and Explanation

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.

The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

Principle of Procedure

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

In the test procedure, a nasopharyngeal or anterior nasal swab specimen is collected and placed into extraction reagent in the Extraction Well of the test device for one minute. During this time the antigen is extracted from disrupted virus particles. The test device is then raised, tapped and laid back down onto a level surface. Through this simple action, the solution of extracted specimen flows onto the test strip and migrates through the pads and membrane of the test strip. The pads contain detector antibodies conjugated to gold dye and the membrane contains immobilized capture antibodies. If SARS-CoV-2, influenza A, and/or influenza B antigens are present in the specimen, they will react with anti-SARS-CoV-2 antibody coupled to gold dye particles and/or anti-influenza antibody coupled to gold dye particles, migrate through the membrane as antigen-antibody-dye complexes, bind to the immobilized capture antibody line(s) on the membrane, and generate a colored line in the specific test line position. The rest of the sample and unbound/bound dye complexes continue to migrate to the Control line position (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 A&B 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 A&B** kit contains enough reagents and materials for 25 tests. The following components are included in a kit.

- **Status COVID-19/Flu A&B** test devices (25): The test strip in each device contains mouse monoclonal antibodies to nucleocapsid protein of influenza A, influenza B and SARS-CoV-2. The device is individually pouched.
- Extraction Reagent in capsules (25): For use with swab specimens; 300 µL of Phosphate buffer with detergents and preservative
- Sterile Swabs (25): For 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)

Materials Required, But Not Provided

- Timer

Precautions/Warnings

- For *in vitro* diagnostic use.
- For prescription use only.
- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- Ensure that there is sufficient lighting for testing and interpretation.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, influenza A, and influenza B, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individual. You may need to purchase additional tests to perform this serial (repeat) testing.**
- **Consistent with serial testing recommendations for SARS-CoV-2, for multi-analyte tests, symptomatic individuals who test positive for influenza A or B on the initial test but test negative for SARS-CoV-2 should be tested again in 48 hours to evaluate for co-infection with SARS-CoV-2 infection.**
- If the individual has had symptoms longer than 5 days you should consider testing them at least three times over 5 days with at least 48 hours between tests.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- Do not use if any of the test kit contents or packaging is damaged.
- Test components are single-use. Do not re-use.
- Do not use kit past its expiration date.
- Do not touch the swab tip.
- Once opened, the test device should be used within 4 hours.
- **Do not read test results before 15 minutes or after 20 minutes. Results read before 15 minutes or after 20 minutes may lead to a false positive, false negative, or invalid result.**
- **Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your [e.g., skin, eyes, nose, or mouth]. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your [e.g., skin, eyes, nose, or mouth], flush with large amounts of water. If irritation persists, seek medical advice: <https://www.poisonhelp.org> or 1-800-222-1222.**

Chemical Name	GHS Code for each Ingredient	Concentrations
Sodium Azide	H300, Acute Tox, Oral H310, Acute Tox, Dermal	0.09 %

- The *Status* COVID-19/Flu A&B test is only intended for use with direct nasopharyngeal or anterior nasal swab specimens and is not validated or authorized for use with viral transport media.

- Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
- Dispose of containers and unused contents in accordance with Federal, State, and Local regulatory requirements.
- Use only the swabs provided for collecting specimens. Other swabs may not work properly.
- Do not smoke, eat or drink in areas in which specimens or kit reagents are handled.
- Wear disposable gloves while handling kit reagents or specimens and thoroughly wash hands afterwards.
- All specimens should be handled as if they are capable of transmitting disease. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens and test devices.
- The **Status™ COVID-19/Flu A&B** test device should remain in its original sealed pouch until ready for use. Do not use the test if the seal is broken or the pouch is damaged.
- If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, the specimen should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health departments for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.
- For more information on EUAs please visit: <https://www.fda.gov/emergencypreparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergencuse-authorization>
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

Storage and Stability

The **Status™ COVID-19/Flu A&B** 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 or anterior nasal swab specimens, only the swab provided in the **Status™ COVID-19/Flu A&B** test kit should be used.
- Use fresh samples for best performance. Freshly collected specimens should be tested immediately. 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.

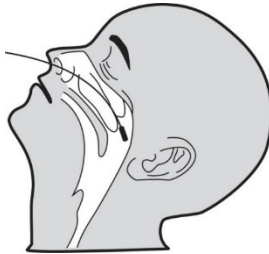
Specimen Collection Procedure

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

To collect Nasopharyngeal Swab Specimen

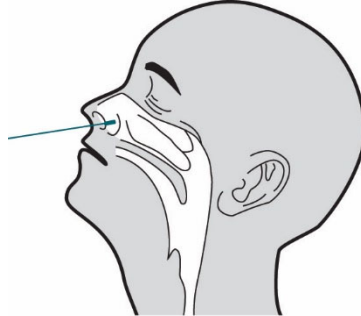
Use a flocked swab provided in the **Status™ COVID-19/Flu A&B kit** only. Tilt patient's head back 70 degrees. Gently and slowly insert a minitip swab with a flexible shaft through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from 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.



To collect Anterior Nasal Swab Specimen

Use a flocked swab provided in the **Status™ COVID-19/Flu A&B kit** only. Insert the entire soft end of the swab into the patient's nostril no more than $\frac{3}{4}$ of an inch (1.5 cm) into the patient's nose. Slowly rotate the swab, gently pressing against the inside of the patient's nostril at least 4 times for a total of 15 seconds. Get as much secretion as possible on the soft end of the swab. Gently remove the swab. Using the same swab, repeat in the second nostril with the same end of the swab.



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.



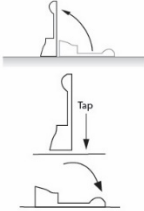
Test Procedure

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.

<p>1</p> 	<p>Tear the tab off the Extraction Reagent Capsule and dispense entire contents into the Extraction Well.</p>
<p>2</p> 	<p>Insert the specimen swab in the Swab Stand.</p> <ul style="list-style-type: none">• Rotate swab 3 times to mix the specimen.• Let stand 1 minute.• Rotate swab 3 times again and discard the swab.
<p>3</p> 	<p>Raise the device upright and let stand 1–2 seconds.</p> <p>Gently tap the device to ensure the liquid flows into the hole.</p> <p>Lay the device back down.</p> <p>Set a timer for 15 minutes.</p>
<p>4</p>	<p>Read test results at 15 minutes.</p> <p>NOTE: False positive or false negative results can occur if the test is not read between 15 and 20 minutes.</p>

Interpretation of Results

Positive: Determination of a positive result is made at fifteen (15) minutes. A reddish-purple Control line (Ctrl 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, and the test is positive. 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 Ctrl positions indicate the presence of SARS-CoV-2 viral antigen in the specimen. Any faint visible reddish-purple lines at A, B, and CoV19 with control line (Ctrl) should be read as positive.

Repeat testing does not need to be performed if patients have a positive result at any time.

A positive CoV19 test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the **Status™ COVID-19/Flu A&B** should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

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(s) 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 (Ctrl position) only, with no Test line at the Flu A, Flu B, or CoV19 positions, indicates that Influenza A, B antigen or SARS-CoV-2 antigen has not been detected, and the test is negative.

Determination of negative results should not be made before 15 minutes.

To increase the chance that the negative result for COVID-19 is accurate, you should:


- **Test again in 48 hours if the individual has symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.**

A negative test result indicates that the virus that causes COVID-19 and influenza virus were not detected in the sample. A negative result does not rule out COVID-19 and Influenza. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19 and flu-like symptoms, e.g., fever, cough, and/or shortness of breath, continue, follow up testing for SARS-CoV-2 or influenza with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.


All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

Invalid: A reddish-purple line should always appear at the Control line position (Ctrl position). If a line does not form at the Control line position in 15 minutes, the test result is invalid. Re-test with a new swab and a new 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 specimen should be re-tested.




A reddish purple CoV19, A and/or B Line(s) with Ctrl Line is positive.




A line:
Influenza
type A




B line:
Influenza
type B




CoV19 line:
COVID-19




A & CoV19 lines:
Influenza type A
& COVID-19*



B & CoV19 lines:
Influenza type B
& COVID-19*




A & B lines:
Influenza
type A & B*



A, B & CoV19 lines:
Influenza type A, B
& COVID-19*



***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.**

Ctrl Line only
Negative (-)



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

No Ctrl Line Invalid

Repeat with new sample and device.

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results.

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Status on First Day of Testing	Day 0 (Test 1)	Day 2 (Test 2)
With Symptoms	<p><u>COVID-19 (-)</u></p> <p>Serial testing recommended for COVID</p> <p><u>Flu A or B (-)</u></p> <p>Flu A or B result is Negative</p>	<p><u>COVID-19 (-)</u></p> <p>COVID result is Negative</p> <p><u>COVID-19 (+)</u></p> <p>COVID-19 result is Positive</p>

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		<u>Flu A or B (-)</u> Flu result is Negative <u>Flu A or B (+)</u> Flu result is Positive
	<u>COVID-19 (-)</u> Serial testing recommended for COVID <u>Flu (+)</u> Flu A or B result is Positive	<u>COVID-19 (-)</u> COVID-19 result is Negative <u>COVID-19 (+)</u> COVID-19 result is Positive <u>Flu A or B (-)</u> Maintain Flu Positive interpretation <u>Flu A or B (+)</u> Flu A or B result is Positive
	<u>COVID-19 (+)</u> COVID Positive <u>Flu A or B (-)</u> Flu A or B Negative	No serial testing recommended
	<u>COVID-19 (+)</u> COVID Positive <u>Flu A or B (+)</u> Flu A or B Positive	No serial testing recommended

Limitations

- These test results are shown as lines of color. Because these lines can be very faint, users with conditions affecting their vision- such as far-sightedness, glaucoma, or color blindness- are encouraged to seek assistance to interpret results accurately (e.g., reading glasses, additional light source, or another person).
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between September 2020 and November 2022. 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.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
- A negative test result does not exclude infection with SARS-CoV-2, influenza A, or B. All **negative test results are presumptive and confirmation with molecular assay may be necessary**. Therefore, the results obtained with the **Status™ COVID-19/Flu A&B** 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.
- If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, the patient may not have COVID-19, however additional follow-up may be needed.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and the individual likely has COVID-19.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- This test detects both viable (live) and nonviable SARS-CoV-2, influenza A, and influenza B. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample 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 A&B** 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 A&B** test has not been established for monitoring antiviral treatment of influenza and SARS-CoV-2.
- Performance of the **Status™ COVID-19/Flu A&B** 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 has not been evaluated for immunocompromised individuals.
- The performance of the **Status™ COVID-19/Flu A&B** 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 A&B** 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 A&B** 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 A&B** test device is working properly, the background in the Test Result Window will be clear, providing a distinct result.

External Quality Control:

Good laboratory practice includes the use of external controls to ensure proper kit performance. It is recommended that external control testing be performed with each new operator and before using a new lot or shipment of **Status™ COVID-19/Flu A&B** 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 A&B** kit contains two external control swabs. Test the control swabs in the same manner as patient specimens. When the positive control is tested, reddish purple lines appear at the C as well as A, B, and 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 A&B** 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 A&B test Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>.

However, to assist in using the *Status*[™] COVID-19/Flu A&B test (“your product” in the conditions below), the relevant Conditions of Authorization are listed below:

- Authorized laboratories¹ 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 A&B” 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.
- 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 LifeSign Customer Support Services (via email: technical@lifesignmed.com, or via phone 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.

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.”

Performance Characteristics

Clinical Performance – Nasopharyngeal swab specimen

A prospective study was performed in which two hundred eighteen (218) direct nasopharyngeal swabs were sequentially enrolled (between September 2020 and April 2021) and tested fresh. The samples were collected from symptomatic patients suspected of infection with COVID-19, at five 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. Two nasopharyngeal swab specimens were collected from each patient; one swab specimen 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 Flu A and B, and the other swab specimen to be tested at the study site.

SARS-CoV-2 Performance (*Status*[™] COVID-19/Flu A&B)

Patient Demographics

Patient demographics (age, the elapsed time from date of symptom onset) are available for the 218 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 (*Status*[™] COVID-19/Flu A&B: SARS-CoV-2 positive = 54)

Age	<i>Status</i> [™] COVID-19/Flu A&B		
	Total #	# COVID-19 Positive	Prevalence
≤ 5 years	16	1	6.3 %
6 to 21 years ¹⁾	68	10	14.7 %
22 to 59 years ²⁾	109	37	33.9 %
≥60 years ³⁾	24	6	25.0 %
Unknown ⁴⁾	1	0	N/A

- 1) One patient was *Status*[™] COVID-19/Flu A&B negative and positive by reference extracted RT-PCR.
- 2) One patient was *Status*[™] COVID-19/Flu A&B negative and positive by reference extracted RT-PCR.
- 3) Two patients were *Status*[™] COVID-19/Flu A&B negative and positive by reference extracted RT-PCR.
- 4) One patient did not provide age information

Specimen Positivity Breakdown Based on Days Post Onset (*Status*™ COVID-19/Flu A&B: SARS-CoV-2 positive = 54)

Days Post Symptom Onset	<i>Status</i> ™ COVID-19/Flu A&B		
	Total # Tested	# COVID-19 Positive	% Positive
0 ¹⁾	38	8	21.1%
1	71	5	7.0%
2	59	16	27.1%
3	25	13	52.0%
4	12	6	50.0%
5 ²⁾	13	6	46.2%

1) Three specimens were *Status*™ COVID-19/Flu A&B negative and positive by reference extracted RT-PCR.

2) One specimen was *Status*™ COVID-19/Flu A&B negative and positive by reference extracted RT-PCR.

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

		Reference Extracted RT-PCR: SARS-CoV-2		
		Positives	Negatives	Total
<i>Status</i> ™ COVID-19/Flu A&B	SARS-CoV-2 Positive	54	0	54
	SARS-CoV-2 Negative	4	160	164
	Total	58	160	218
Positive Percent Agreement (PPA) = 93.1% (95% CI = 83.6 to 97.3%)				
Negative Percent Agreement (NPA) = 100% (95% CI = 97.7 to 100%)				

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

		Reference Extracted RT-PCR: Influenza A		
		Positives	Negatives	Total
Status™ COVID-19/Flu A&B	Influenza A Positive	0	0	0
	Influenza A Negative	0	218	218
	Total	0	218	218
Positive Percent Agreement (PPA) = N/A				
Negative Percent Agreement (NPA) = 100% (95% CI = 98.3 to 100%)				

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

		Reference Extracted RT-PCR: Influenza B		
		Positives	Negatives	Total
Status™ COVID-19/Flu A&B	Influenza B Positive	0	0	0
	Influenza B Negative	0	218	218
	Total	0	218	218
Positive Percent Agreement (PPA) = N/A				
Negative Percent Agreement (NPA) = 100% (95% CI = 98.3 to 100%)				

Clinical Performance – Anterior nasal swab specimen

A prospective study was performed in which two hundred ninety-seven (297) evaluable direct anterior nasal swab specimens were sequentially enrolled (between February 2021 and April 2021, and between February 2022 and November 2022) and tested fresh. The samples were collected from symptomatic patients suspected of infection with COVID-19 and flu, at five 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. The clinical performance between February 2021 and April 2021, one nasopharyngeal swab specimen and anterior nasal swab specimen were collected from each patient; one nasopharyngeal 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, influenza A and influenza B and one anterior nasal swab specimen to be tested at the study site. The clinical performance between February 2022 and November 2022, two anterior nasal swab specimens were collected from each patient; one anterior nasal swab to be tested using a comparator method and the other anterior nasal swab specimen to be tested at the study site.

Anterior nasal swab samples for Status™ COVID-19/Flu A&B vs Nasopharyngeal swab samples for comparator method

Patient Demographics

Patient demographics (age, the elapsed time from date of symptom onset) are available for the 193 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 (Status™ COVID-19/Flu A&B: SARS-CoV-2 positive = 45)

Age	Status™ COVID-19/Flu A&B		
	Total #	# COVID-19 Positive	% Positive
≤ 5 years	16	1	6.3%
6 to 21 years ¹⁾	65	9	13.8%
22 to 59 years ²⁾	94	31	33.0%
≥60 years ³⁾	18	4	22.2%

1) One patient was Status™ COVID-19/Flu A&B negative and positive by reference extracted RT-PCR.

2) One patient was Status™ COVID-19/Flu A&B negative and positive by reference extracted RT-PCR.

3) One patient was Status™ COVID-19/Flu A&B negative and positive by reference extracted RT-PCR.

Specimen Positivity Breakdown Based on Days Post Onset (*Status*™ COVID-19/Flu A&B test: SARS-CoV-2 positive = 45)

Days Post Symptom Onset	<i>Status</i> ™ COVID-19/Flu A&B		
	Total # Tested	# COVID-19 Positive	% Positive
0 ¹⁾	32	5	15.6%
1	70	4	5.7%
2	53	15	28.3%
3	21	11	52.4%
4	7	4	57.1%
5	10	6	60.0%

1) Three specimens were *Status*™ COVID-19/Flu A&B negative and positive by reference extracted RT-PCR.

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

		Reference Extracted RT-PCR: SARS-CoV-2		
		Positives	Negatives	Total
<i>Status</i>™ COVID-19/Flu A&B	SARS-CoV-2 Positive	45	0	45
	SARS-CoV-2 Negative	3	145	148
	Total	48	145	193
Positive Percent Agreement (PPA) = 93.8% (95% CI = 83.2 to 97.9%)				
Negative Percent Agreement (NPA) = 100% (95% CI = 97.4 to 100%)				

Approximately 20.8 % (10 out of 48 positive specimens) of the clinical specimens were low positives (i.e., RT-PCR Ct counts ≥ 30).

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

		Reference Extracted RT-PCR: Influenza A		
		Positives	Negatives	Total
Status™ COVID-19/Flu A&B	Influenza A Positive	0	0	0
	Influenza A Negative	0	193	193
Total		0	193	193
Positive Percent Agreement (PPA) = N/A				
Negative Percent Agreement (NPA) = 100% (95% CI = 98.1 to 100%)				

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

		Reference Extracted RT-PCR: Influenza B		
		Positives	Negatives	Total
Status™ COVID-19/Flu A&B	Influenza B Positive	0	0	0
	Influenza B Negative	0	193	193
Total		0	193	193
Positive Percent Agreement (PPA) = N/A				
Negative Percent Agreement (NPA) = 100% (95% CI = 98.1 to 100%)				

Anterior nasal swab samples for Status™ COVID-19/Flu A&B f vs Anterior nasal swab samples for comparator method

Patient Demographics

Patient demographics (age, the elapsed time from date of symptom onset) are available for the 104 patients participating in this study. COVID-19 and flu Positive results are broken down by age and days post symptom onset in the tables below.

Patient Demographics (*Status*™ COVID-19/Flu A&B: SARS-CoV-2 positive = 11)

Age	Status™ COVID-19/Flu A&B		
	Total #	# COVID-19 Positive	% Positive
≤ 5 years	6	0	N/A
6 to 21 years	42	4	9.5%
22 to 59 years ¹⁾	45	3	6.7%
≥60 years	11	4	36.4%

1) One patient was *Status*™ COVID-19/Flu A&B negative and positive by reference extracted RT-PCR.

Specimen Positivity Breakdown Based on Days Post Symptom Onset (*Status*™ COVID-19/Flu A&B test: SARS-CoV-2 positive = 11)

Days Post Symptom Onset	Status™ COVID-19/Flu A&B		
	Total # Tested	# COVID-19 Positive	% Positive
0 ¹⁾	20	1	5.0%
1	32	4	12.5%
2	31	2	6.5%
3	14	2	14.3%
4	4	2	50.0%
5	3	0	N/A

1) One patient was *Status*™ COVID-19/Flu A&B negative and positive by reference extracted RT-PCR

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

		Reference Extracted RT-PCR: SARS-CoV-2		
		Positives	Negatives	Total
Status™ COVID-19/Flu A&B	SARS-CoV-2 Positive	11	0	11
	SARS-CoV-2 Negative	1	92	93
Total		12	92	104
Positive Percent Agreement (PPA) = 91.7% (95% CI = 64.6 to 98.5%)				
Negative Percent Agreement (NPA) = 100% (95% CI = 96.0 to 100%)				

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

		Reference Extracted RT-PCR: Influenza A		
		Positives	Negatives	Total
Status™ COVID-19/Flu A&B	Influenza A Positive	54	0	54
	Influenza A Negative	3	47	50
Total		57	47	104
Positive Percent Agreement (PPA) = 94.7% (95% CI = 85.6 to 98.2%)				
Negative Percent Agreement (NPA) = 100% (95% CI = 92.4 to 100%)				

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

		Reference Extracted RT-PCR: Influenza B		
		Positives	Negatives	Total
Status™ COVID-19/Flu A&B	Influenza B Positive	0	0	0
	Influenza B Negative	0	104	104
Total		0	104	104
Positive Percent Agreement (PPA) = N/A				
Negative Percent Agreement (NPA) = 100% (95% CI = 98.1 to 100%)				

Combined Performance for Anterior nasal swab specimens.

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

		Comparator: RT-PCR: SARS-CoV-2		
		Positives	Negatives	Total
Status™ COVID-19/Flu A&B test	SARS-CoV-2 Positives	56	0	56
	SARS-CoV-2 Negatives	4	237	241
	Total	60	237	297
Positive Percent Agreement (PPA) = 93.3% (95% CI = 84.1 to 97.4%)				
Negative Percent Agreement (NPA) = 100% (95% CI = 98.4 to 100%)				

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

		Comparator: RT-PCR: Influenza A		
		Positives	Negatives	Total
Status™ COVID-19/Flu A&B test	Influenza A Positives	54	0	54
	Influenza A Negatives	3	240	243
	Total	57	240	297
Positive Percent Agreement (PPA) = 94.7% (95% CI = 85.6 to 98.2%)				
Negative Percent Agreement (NPA) = 100% (95% CI = 98.4 to 100%)				

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

		Comparator: RT-PCR: Influenza B		
		Positives	Negatives	Total
Status™ COVID-19/Flu A&B test	Influenza B Positives	0	0	0
	Influenza B Negatives	0	297	297
	Total	0	297	297
Positive Percent Agreement (PPA) = N/A				
Negative Percent Agreement (NPA) = 100% (95% CI = 98.7 to 100%)				

In the absence of fresh clinical Influenza 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 A&B** test and the *Status* Flu A&B test. Results from the testing of eleven (11) influenza B positive samples were combined and analyzed.

Status™ COVID-19/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 /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	

Serial testing for SARS-CoV-2

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS-CoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 – 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RT-PCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Pre-symptomatic subjects were included in the positive percent agreement (PPA) of asymptomatic individuals, if they were asymptomatic on the first day of antigen testing, regardless of whether they developed symptoms at any time after the first day of testing. Performance of the antigen test with serial testing in individuals is described in Table below.

Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.

DAYS AFTER FIRST PCR POSITIVE TEST RESULT	ASYMPTOMATIC ON FIRST DAY OF TESTING			SYMPTOMATIC ON FIRST DAY OF TESTING		
	Ag Positive / PCR Positive (Antigen Test Performance % PPA)					
	1 Test	2 Tests	3 Tests	1 Test	2 Tests	3 Tests
0	9/97	35/89	44/78	34/57	47/51	44/47
	(9.3%)	(39.3%)	(56.4%)	(59.6%)	(92.2%)	(93.6%)
2	17/34	23/34	25/32	58/62	59/60	43/43
	(50.0%)	(67.6%)	(78.1%)	(93.5%)	(98.3%)	(100%)
4	16/21	15/20	13/15	55/58	53/54	39/40
	(76.2%)	(75.0%)	(86.7%)	(94.8%)	(98.1%)	(97.5%)
6	20/28	21/27	16/18	27/34	26/33	22/27
	(71.4%)	(77.8%)	(88.9%)	(79.4%)	(78.8%)	(81.5%)
8	13/23	13/22	4/11	12/17	12/17	7/11
	(56.5%)	(59.1%)	(36.4%)	(70.6%)	(70.6%)	(63.6%)
10	5/9	5/8		4/9	3/7	
	(55.6%)	(62.5%)		(44.4%)	(42.9%)	

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

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

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

The **Status™ COVID-19/Flu A&B** 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 anterior nasal swab specimens were included in the performance analyses below.

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

<i>Status</i> Flu A+ B	Virus Culture Results			Performance
	Flu A Positive	Flu A Negative	Total	
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.

<i>Status</i> Flu A+ B	Virus Culture Results			Performance
	Flu B Positive	Flu B Negative	Total	
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 anterior nasal swabs samples that produced concordant results between *Status* Flu A&B and viral culture (a subset of the concordant nasopharyngeal/anterior 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.

Performance³ of the *Status* Flu A&B against the PCR comparator assay for all nasopharyngeal and anterior nasal swab samples are presented in the tables below.

Nasopharyngeal and Anterior Nasal Swab Samples (combined): Comparison with PCR

Status Flu A+ B	PCR Results			Performance
	Flu A Positive	Flu A Negative	Total	
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	

Status Flu A+ B	PCR Results			Performance
	Flu B Positive	Flu B Negative	Total	
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 anterior nasal swab specimens when used by operators at CLIA-waived sites. The nasopharyngeal and anterior 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 and Anterior Nasal Swab Samples (combined): Comparison with PCR

Status Flu A+ B	PCR Results			Performance
	Flu A Positive	Flu A Negative	Total	
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	

Status Flu A+ B	PCR Results			Performance
	Flu B Positive	Flu B Negative	Total	
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 and Anterior Nasal Swab Samples (combined): Comparison with PCR

Status	PCR Results			Performance
	Flu A Positive	Flu A Negative	Total	
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	

Status	PCR Results			Performance
	Flu B Positive	Flu B Negative	Total	
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 A&B** 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 A&B** 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. Based upon the testing procedure for this study, the SARS-CoV-2 LoD of 2.7×10^3 TCID₅₀/mL equates to 1.35×10^2 TCID₅₀/swab or 3.83×10^3 TCID₅₀/extraction reagent. The LoD for all three target viruses is summarized in the table below.

Virus Strains	Sources	LoD	LoD	#Positive/#Total	% Positive
SARS-COV-2 USA-WA1/2020	ATCC® Number, VR- 1986HK™	2.7×10^3 TCID ₅₀ /mL	3.83×10^2 TCID ₅₀ /swab	20/20	100
Influenza A Victoria/361/11(H3N2)	Zeptomatrix, Cat# 0810240CF	4.51×10^1 TCID ₅₀ /mL	6.40 TCID ₅₀ /swab	20/20	100
Influenza A A/California/07/2009(H1N1)	ATCC, Cat# VR-1894	2.08×10^5 CEID ₅₀ /mL	2.95×10^4 CEID ₅₀ /swab	20/20	100

Influenza B Victoria/504/00	Zeptomatrix, Cat# 0810571CF	5.64 x 10 ² TCID ₅₀ /mL	8.00 x 10 ¹ TCID ₅₀ /swab	20/20	100
Influenza B Yamagata/16/88	Zeptomatrix, Cat# 0810518CF	2.72 x 10 ² TCID ₅₀ /mL	3.86 x 10 ¹ TCID ₅₀ /swab	20/20	100

Analytical Reactivity/ Inclusivity

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

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

The 2021 CDC Human Influenza Panel was tested with the **Status™ COVID-19/Flu A&B** 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 in five replicates until two consecutive dilutions were negative. Test results are tabulated next.

CDC human influenza virus A panel (VP2021) 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)										
		Concentration	5	2x10 ^{7.3}	4x10 ^{6.3}	8x10 ^{5.3}	1.6x10 ^{4.3}	3.2x10 ^{3.3}	6.4x10 ^{2.3}	1.28x10 ^{1.3}	2.56x10 ^{0.3}	
A(H3N2)	A/Perth/16/2009	Status Flu A&B	n/a	5/5	5/5	5/5	5/5	5/5	4/5	0/5	0/5	
		Status™ COVID-19/Flu A&B	n/a	5/5	5/5	5/5	5/5	5/5	4/5	0/5	0/5	
		Concentration	10 ^{8.5}	2x10 ^{7.5}	4x10 ^{6.5}	8x10 ^{5.5}	1.6x10 ^{4.5}	3.2x10 ^{3.5}	6.4x10 ^{2.5}	1.28x10 ^{1.5}	2.56x10 ^{0.5}	
A(H3N2)	A/Tasmania/503/2020	Status Flu A&B	n/a	5/5	3/5	0/5	0/5	5/5	3/5	0/5	0/5	
		Status™ COVID-19/Flu A&B	n/a	5/5	3/5	0/5	0/5	5/5	4/5	0/5	0/5	
		Concentration	10 ^{9.2}	2x10 ^{8.2}	4x10 ^{7.2}	8x10 ^{6.2}	1.6x10 ^{5.2}	3.2x10 ^{4.2}	6.4x10 ^{3.2}	n/a	n/a	
A(H1N1) pdm09		Status Flu A&B	n/a	5/5	5/5	5/5	4/5	0/5	0/5	n/a	n/a	
		Concentration	10 ^{9.2}	2x10 ^{8.2}	4x10 ^{7.2}	8x10 ^{6.2}	1.6x10 ^{5.2}	3.2x10 ^{4.2}	6.4x10 ^{3.2}	n/a	n/a	

	A/Christ Church /16/2010	Status™ COVID-19/Flu A&B	n/a	5/5	5/5	5/5	4/5	0/5	0/5	n/a	n/a
A(H1N1) pdm09	A/Victoria/257 0/2019	Concentration	10 ^{8.2}	2x10 ^{7.2}	4x10 ^{6.2}	8x10 ^{5.2}	1.6x10 ^{4.2}	3.2x10 ^{3.2}	6.4x10 ^{2.2}	n/a	n/a
		Status Flu A&B	n/a	5/5	5/5	5/5	3/5	0/5	0/5	n/a	n/a
		Status™ COVID-19/Flu A&B	n/a	5/5	5/5	5/5	3/5	0/5	0/5	n/a	n/a

CDC human influenza virus B panel (VP2021) test result (Swab sample)

B (Victoria lineage)	B/Michigan/09 /2011	Concentration	10 ^{6.9}	2x10 ^{5.9}	4x10 ^{4.9}	8x10 ^{3.9}	1.6x10 ^{2.9}	3.2x10 ^{1.9}	6.4x10 ^{0.9}	n/a
		Status Flu A&B	n/a	5/5	5/5	5/5	3/5	0/5	0/5	n/a
		Status™ COVID-19/Flu A&B	n/a	5/5	5/5	5/5	3/5	0/5	0/5	n/a
B (Victoria lineage)	B/Washington /02/2019	Concentration	10 ^{9.3}	2x10 ^{8.3}	4x10 ^{7.3}	8x10 ^{6.3}	1.6x 10 ^{5.3}	3.2x10 ^{4.3}	6.4x10 ^{3.3}	n/a
		Status Flu A&B	n/a	5/5	5/5	5/5	4/5	0/5	0/5	n/a
		Status™ COVID-19/Flu A&B	n/a	5/5	5/5	5/5	4/5	0/5	0/5	n/a
B (Yamagata lineage)	B/Texas/81/2 016	Concentration	10 ^{8.1}	2x10 ^{7.1}	4x10 ^{6.1}	8x10 ^{5.1}	1.6x10 ^{4.1}	3.2x10 ^{3.1}	6.4x10 ^{2.1}	n/a
		Status Flu A&B	n/a	5/5	5/5	5/5	5/5	0/5	0/5	n/a
		Status™ COVID-19/Flu A&B	n/a	5/5	5/5	5/5	5/5	0/5	0/5	n/a
B (Yamagata lineage)	B/Phuket/307 3/2013	Concentration	10 ^{9.9}	2x10 ^{8.9}	4x10 ^{7.9}	8x10 ^{6.9}	1.6x10 ^{5.9}	3.2x10 ^{4.9}	6.4x10 ^{3.9}	1.28x10 ^{2.9}
		Status Flu A&B	n/a	5/5	5/5	3/5	5/5	1/5	0/5	0/5
		Status™ COVID-19/Flu A&B	n/a	5/5	5/5	3/5	5/5	2/5	0/5	0/5

The analytical inclusivity for influenza A and B was demonstrated with StatusFluA&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)

Cross-reactivity of the Status™ COVID-19/Flu A&B test was evaluated by testing a panel of related pathogens, high prevalence disease agents, and normal or pathogenic flora that are reasonably likely to be encountered in clinical specimens and could potentially cross-react with the Status™ COVID-19/Flu A&B test including ten (10) bacteria, eighteen (18) viruses, and one (1) negative matrix. Each organism and virus were tested in the absence or presence of heat inactivated SARS-CoV- 2, Influenza A, and B at 3 x LoD. No cross-reactivity was seen with the listed microorganisms when tested at the concentration presented in the table below. Cross-Reactivity-SARS-CoV-2

Potential Cross-reactant	Concentration tested
Human coronavirus 229E	1.0 x 10 ⁵ TCID ₅₀ /mL
Human coronavirus OC43	1.0 x 10 ⁵ TCID ₅₀ /mL
Human coronavirus 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
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
<i>Streptococcus pneumoniae</i>	2.0 x 10 ⁴ cfu/mL
<i>Streptococcus pyogenes</i> , Bruno	4.0 x 10 ⁶ cfu/mL
<i>Candida albicans</i>	1.0 x 10 ⁶ cfu/mL
<i>Bordetella pertussis</i> , 18323	1.0 x 10 ⁶ cfu/mL
<i>Mycoplasma pneumoniae</i>	1.0 x 10 ⁶ cfu/mL
<i>Chlamydia pneumoniae</i> TW-183	1.0 x 10 ⁶ IFU/mL
<i>Legionella pneumophila</i>	1.0 x 10 ⁶ cfu/mL
<i>Pneumocystis jirovecii</i>	1.0 x 10 ⁶ cfu/mL
<i>Staphylococcus epidermidis</i>	1.0 x 10 ⁶ cfu/mL
<i>Staphylococcus aureus</i>	1.0 x 10 ⁶ cfu/mL
Pooled human nasal wash	NA

Cross-Reactivity-Influenza A

Potential Cross-reactant	Concentration tested
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
<i>Haemophilus influenza</i>	4 x 10 ⁴ cfu/mL
<i>Streptococcus pneumoniae</i>	2.0 x 10 ⁴ cfu/mL
<i>Streptococcus pyogenes</i> , Bruno	4.0 x 10 ⁶ cfu/mL
<i>Candida albicans</i>	1.0 x 10 ⁶ cfu/mL
<i>Bordetella pertussis</i> , 18323	1.0 x 10 ⁶ cfu/mL
<i>Mycoplasma pneumoniae</i>	1.0 x 10 ⁶ cfu/mL
<i>Chlamydia pneumoniae</i> TW-183	1.0 x 10 ⁶ IFU/mL
<i>Legionella pneumophila</i>	1.0 x 10 ⁶ cfu/mL
<i>Pneumocystis jirovecii</i>	1.0 x 10 ⁶ cfu/mL
<i>Staphylococcus epidermidis</i>	1.0 x 10 ⁶ cfu/mL
<i>Staphylococcus aureus</i>	1.0 x 10 ⁶ cfu/mL
Pooled human nasal wash	NA

Cross-Reactivity- Influenza B

Potential Cross-reactant	Concentration tested
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
<i>Haemophilus influenza</i>	4 x 10 ⁴ cfu/mL
<i>Streptococcus pneumoniae</i>	2.0 x 10 ⁴ cfu/mL
<i>Streptococcus pyogenes</i> , Bruno	4.0 x 10 ⁶ cfu/mL
<i>Candida albicans</i>	1.0 x 10 ⁶ cfu/mL
<i>Bordetella pertussis</i> , 18323	1.0 x 10 ⁶ cfu/mL
<i>Mycoplasma pneumoniae</i>	1.0 x 10 ⁶ cfu/mL
<i>Chlamydia pneumoniae</i> TW-183	1.0 x 10 ⁶ IFU/mL
<i>Legionella pneumophila</i>	1.0 x 10 ⁶ cfu/mL
<i>Pneumocystis jirovecii</i>	1.0 x 10 ⁶ cfu/mL
<i>Staphylococcus epidermidis</i>	1.0 x 10 ⁶ cfu/mL
<i>Staphylococcus aureus</i>	1.0 x 10 ⁶ cfu/mL
Pooled human nasal wash	NA

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, however, cross-reactivity cannot be ruled out.
- No significant similarity found between SARS-Coronavirus and Influenza A or B, however, cross-reactivity cannot be ruled out.
- No significant similarity found between MERS-coronavirus and Influenza A or B, however, cross-reactivity cannot be ruled out.
- No significant similarity found between Human coronavirus HKU and Influenza A or B, however, cross-reactivity cannot 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 A&B** test. No interference was seen with the listed substances when tested at the concentration presented in the table below.

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)	Galphimia glauca 6X, Luffa operculata 6X, Sabadilla 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 A&B** test, for the SARS-CoV-2, Influenza A and B viral strains at the concentration listed below.

Virus Type	Viral Strain	Concentration tested
SARS-CoV-2	USA-WA1/2020	1.15 x 10 ⁷ TCID ₅₀ /mL
Influenza A (H3N2)	A/California/2/2014	5.8 x 10 ⁵ TCID ₅₀ /mL
Influenza A(H3N2)	A/Hong Kong/8/68	1.26 x 10 ⁶ TCID ₅₀ /mL
Influenza A (H3N2)	Victoria/361/11	1.41 x 10 ⁵ TCID ₅₀ /mL
Influenza A (H1N1)	A/California/07/2009	5.2 x 10 ⁷ CEID ₅₀ /mL
Influenza B	B/Russia/69	1.5 x 10 ⁶ CEID ₅₀ /mL
Influenza B	B/Florida/02/06	1.05 x 10 ⁶ TCID ₅₀ /mL
Influenza B	B/Victoria/504/00	1.41 x 10 ⁵ TCID ₅₀ /mL
Influenza B	B/Yamagata/16/88	1.70 x 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 and influenza A and influenza B at levels near LOD were tested 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 tables 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 x 10 ⁵ TCID ₅₀ /mL	SARS-CoV-2 USA-WA1/2020	4.0 x 10 ³ TCID ₅₀ /mL	100%
Influenza A A/Hong Kong/8/68(H3N2)	1.0 x 10 ⁵ TCID ₅₀ /mL	SARS-CoV-2 USA-WA1/2020	4.0 x 10 ³ TCID ₅₀ /mL	100%
Influenza A (H3N2) Victoria/361/11	1.0 x 10 ⁵ TCID ₅₀ /mL	SARS-CoV-2 USA-WA1/2020	4.0 x 10 ³ TCID ₅₀ /mL	100%
Influenza A (H1N1) A/California/07/2009	1.0 x 10 ⁶ CEID 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 A (H3N2) Victoria/361/11	6.5 x 10 ¹ TCID ₅₀ /mL	100%
SARS-CoV-2 USA-WA1/2020	1.0 x 10 ⁵ TCID ₅₀ /mL	Influenza A (H1N1) A/California/07/2009	3.0 x 10 ⁵ CEID ₅₀ /mL	100%

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)

References

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



Instructions for Use (Read)

REF

Catalog Number



Store at

SWAB

Swab



Expiration Date

PRC

Procedure Card



Do not reuse.

IVD

For *in vitro* Diagnostic Use

LOT

Lot Number

CONT +

Positive Control

CONT -

Negative Control

CONT Contents

DEV Test Device

IFU Instruction for Use

CAP Reagent Capsule

MTD COVID-19/FLU



Manufacturer

DIST Distributed by

EC **REP** Authorized Representative

CE CE Mark

An *in vitro* immunochromatographic assay for the qualitative detection of SARS-CoV-2, influenza type A and type B antigens directly from nasal specimens



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QUICK REFERENCE INSTRUCTIONS

P-5383-E

Status™ COVID-19/Flu A&B Anterior Nasal or Nasopharyngeal Swab Specimens



Study the Package Insert thoroughly before using Quick Reference Instructions. This is not a complete Package Insert.

	<p>Tear the tab off the Extraction Reagent Capsule and dispense entire contents into the Extraction Well.</p>
	<p>Insert the specimen swab in the Swab Stand.</p> <ul style="list-style-type: none">• Rotate swab 3 times to mix the specimen.• Let stand 1 minute.• Rotate swab 3 times again and discard the swab.
	<p>Raise the device upright and let stand 1–2 seconds.</p> <p>Gently tap the device to ensure the liquid flows into the hole.</p> <p>Lay the device back down.</p> <p>Set a timer for 15 minutes.</p>
	<p>Read test results at 15 minutes.</p> <p>NOTE: False positive or false negative results can occur if the test is not read between 15 and 20 minutes.</p>
<ul style="list-style-type: none">• For use under the Emergency Use Authorization (EUA) only• For in vitro diagnostic use• Rx only• Refer to the Package Insert for complete instructions. Read the complete test procedure, including recommended Quality Control procedures, before performing the test.• All clinical specimens must be at room temperature before beginning the assay.• Performing the assay outside the time and temperature ranges provided may produce invalid results.• Assays not performed within the established time and temperature ranges must be repeated.• Expiration date: Check expiration on each individual test package or outer box before using. Do not use any test past the expiration date on the label.• Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing. Consistent with serial testing recommendations for SARS-CoV-2, for multi-analyte tests, symptomatic individuals who test positive for influenza A or B on the initial test but test negative for SARS-CoV-2 should be tested again in 48 hours to evaluate for co-infection with SARS-CoV-2 infection.• Ensure that there is sufficient lighting for testing and interpretation.	
<p>Internal Quality Control:</p> <p>Each Status™ COVID-19/Flu A&B test device has built-in controls. The Control line at the Ctrl 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.</p> <p>External Quality Control:</p> <p>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 A&B 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.</p>	
	<p>A reddish purple CoV19, A and/or B Line(s) with Ctrl Line is positive.</p> <p>Ctrl Line only Negative (-)</p> <p>Negative Results are presumptive and may need to be confirmed with a molecular assay.</p>
	<p>No Ctrl Line Invalid</p> <p>Repeat with new sample and device.</p>
<p>*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.</p>	

INTERPRETATION OF RESULTS

For serial testing results interpretation, please see SECTION 'Interpretation of Results' in the Instructions for Use.

Positive:

Determination of a positive result is made at fifteen (15) minutes. If there are reddish-purple Control line (Ctrl position) and a reddish-purple Test line (Flu A, Flu B or CoV19 position), it indicates that Influenza A, B and/or SARS-CoV-2 antigen has been detected, and the test is positive. Lines at the A and Ctrl positions indicate the presence of Influenza type A viral antigen, lines at the B and Ctrl positions indicate the presence of Influenza type B viral antigen, and lines at the CoV19 and Ctrl positions indicate the presence of SARS-CoV-2 viral antigen in the specimen. Any faint visible reddish-purple lines at A, B, and CoV19 with control line (Ctrl) should be read as positive. Repeat testing does not need to be performed if patients have a positive result at any time.

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the **Status™ COVID-19/Flu A&B** should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

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:

If there is only a reddish purple control line (Ctrl position) with no test line at the Flu A, Flu B, CoV19 positions, it indicates that the Influenza A, B antigen, or SARS-CoV-2 antigen has not been detected, and the test result is negative. Determination of negative results should not be made before 15 minutes.

To increase the chance that the negative result for COVID-19 is accurate, you should:

- Test again in 48 hours if the individual has symptoms on the first day of testing.
- Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.

A negative test result indicates that the virus that causes COVID-19 and influenza virus were not detected in the sample. A negative result does not rule out COVID-19 and Influenza. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19 and flu-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 or influenza with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

Invalid:

A reddish-purple line should always appear at the Control line position (Ctrl position). If a line does not form at the Control line position in 15 minutes, the test result is invalid. Re-test with a new swab and new 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.

INTENDED USE

Status™ COVID-19/Flu A&B test is a lateral flow immunoassay intended for the in vitro rapid, simultaneous qualitative detection and differentiation of nucleocapsid protein antigen from SARS-CoV-2, influenza A and/or influenza B directly from nasopharyngeal or anterior nasal swab specimens collected from individuals, who are suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider- within the first five (5) days of symptom onset when tested at least twice over three days with at least 48 hours between tests. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high, or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

The **Status™ COVID-19/Flu A&B** does not differentiate between SARS-CoV or SARS-CoV-2 viruses.

Results are for the simultaneous in vitro detection and differentiation of nucleocapsid protein antigens of SARS-CoV-2, influenza A and influenza B, and is not intended to detect influenza C antigens. These viral antigens are generally detectable in nasopharyngeal or anterior nasal 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 definitive 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.

All negative SARS-CoV-2 results are 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 measures such as isolating from others and wearing masks. 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.

All negative influenza A and B test results are 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.

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 A&B** is intended for use by medical professionals or trained operators who are proficient in performing tests in point of care settings.

The **Status™ COVID-19/Flu A&B** test is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

EMERGENCY USE AUTHORIZATION – WARNING AND PRECAUTIONS

Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.

- In the USA this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization 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 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.
- Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.

ASSISTANCE

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

Test system problems may also be reported to the FDA through the MedWatch medical products reporting program (phone: 800.FDA.1088; fax: 800.FDA.0178; <http://www.fda.gov/medwatch>).



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