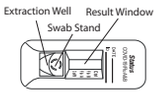
QUICK REFERENCE INSTRUCTIONS

P-5383-E

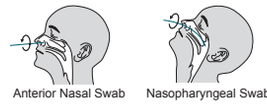
Status™ COVID-19/Flu A&B Anterior Nasal or Nasopharyngeal Swab Specimens

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

TEST DEVICE



SAMPLE COLLECTION



PROCEDURE

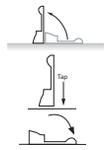
1. 

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

2. 

Insert the specimen swab in the Swab Stand.

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

3. 

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

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

Lay the device back down.

Set a timer for 15 minutes.

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

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

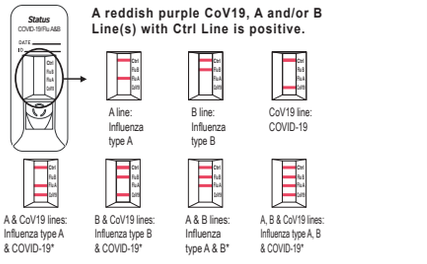
- For use under the Emergency Use Authorization (EUA) only
- For in vitro diagnostic use
- Rx only
- Refer to the Package Insert for complete instructions. Read the complete test procedure, including recommended Quality Control procedures, before performing the test.
- All clinical specimens must be 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 ymptomatic 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.

QUALITY CONTROL

Internal Quality Control:
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.

External Quality Control:
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.

INTERPRETATION OF RESULTS



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.

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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).