QUICK REFERENCE INSTRUCTIONS

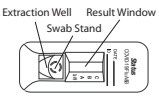
P-5383-A

Status™ COVID-19/Flu A&B

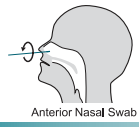
Anterior Nasal or Nasopharyngeal Swab Specimens

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

TEST DEVICE



SAMPLE COLLECTION



PROCEDURE

❶

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

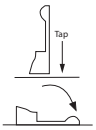
❷

Insert the specimen swab in the Swab Stand.

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

❸

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



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

Lay the device back down.

Set a timer for 15 minutes.

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

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

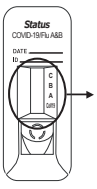
- For use under the Emergency Use Authorization (EUA) only
- For in vitro diagnostic use
- Rx only
- Refer to the Package Insert for complete instructions. Read the complete test procedure, including recommended Quality Control procedures, before performing the test.
- All clinical specimens must be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

QUALITY CONTROL

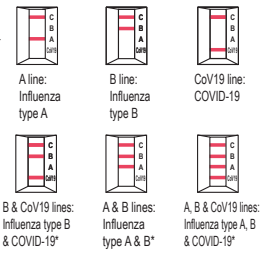
Internal Quality Control:
Each Status™ COVID-19/Flu A&B test device has built-in controls. The Control line at the C position can be considered as an internal positive procedural control; i.e., a proper amount of sample was used, sample was properly added to the Extraction Well, sample migrated properly, 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.

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 C Line is positive.

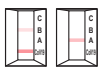


***NOTE: Co-infection with Influenza A, B and/or SARS-CoV-2 is rare. If results are positive for more than one antigen, i.e., Flu A, B and/or COVID-19, the patient specimens should be re-tested.**

C Line only
Negative (–)

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

No C Line
Invalid



Repeat with new sample and device.

CE

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IVD

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Princeton BioMeditech Corp.
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Monmouth Junction, NJ 08852

INTERPRETATION OF RESULTS

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

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

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

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

Invalid:
A reddish purple line should always appear at the Control line position (C position). If a line does not form at the Control line position in 15 minutes, the test result is invalid and the test should be repeated with a new Status™ COVID-19/Flu A&B 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. Repeatable multiple positive results (more than one test line) should be confirmed by molecular assay before reporting results.

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 antigen from SARS-CoV-2, influenza A and/or influenza B directly from anterior nasal or nasopharyngeal swab specimens obtained from patients who are suspected of COVID-19 by their healthcare provider, within the first five days of onset of symptoms. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high, or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the simultaneous identification of nucleocapsid antigens of SARS-CoV-2, influenza A and influenza B. These viral antigens are generally detectable in anterior nasal or nasopharyngeal swab samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but the clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of the disease. Laboratories within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities.

Negative SARS-CoV-2 results should be treated as presumptive, and do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary, for patient management.

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

Performance characteristics for influenza A and B were established during the 2007-2009 and the 2014-2016 influenza seasons when influenza A/H1N1, A/H1N1 pandemic, A/H3N2, influenza B/Victoria lineage, and B/Yamagata lineage were the predominant influenza viruses in circulation according to the Flu Activity & Surveillance reports from the CDC. When other influenza viruses are emerging, performance characteristics may vary. The performance of this test for SARS-CoV-2 was established based on the evaluation of a limited number of clinical specimens collected between September 2020 and April 2021. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

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

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

Refer to the Package Insert for Warnings and Precautions, Specimen Collection and Handling, and Quality Control.

EMERGENCY USE AUTHORIZATION – WARNING AND PRECAUTIONS

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories: use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet 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. 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.

In the USA, 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 the virus that causes 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.

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).