QUICK REFERENCE INSTRUCTIONS

P-5383-F

Status™ COVID-19/Flu A&B

* CLIA waived for use with nasopharyngeal and anterior nasal swabs.
* Laboratories with Certificate of Waiver must follow the manufacturer's instructions for performing the test.
* Failure to follow the instructions or any modification to the manufacturer's instructions will result in the test being classified as high complexity.

For *in vitro* Diagnostic Use For Rx Use Only For Use with Kit Provided Swab

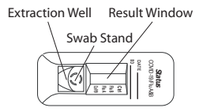
Study the Package Insert thoroughly before using Quick Reference Instructions for test procedure, warnings, precautions, limitations section. This is not a complete Package Insert.

This test has not been validated for use by those with color-impaired vision.

INTENDED USE

The ***Status***™ **COVID-19/Flu A&B** test is a lateral flow immunoassay intended for the qualitative detection and differentiation of influenza A and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly from nasopharyngeal (NP) or anterior nasal swab (ANS) specimens from individuals with signs and symptoms of respiratory tract infection. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.
All negative results are presumptive and should be confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out infection with influenza or SARS-CoV-2 and should not be used as the sole basis for treatment or patient management decisions.
Positive results do not rule out bacterial infection or co-infection with other viruses.

TEST DEVICE



SAMPLE COLLECTION

Anterior Nasal Swab Nasopharyngeal Swab

Samples should be tested immediately after collection.

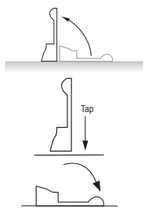
PROCEDURE

1 

Tear the tab off the Extraction Reagent Vial 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.

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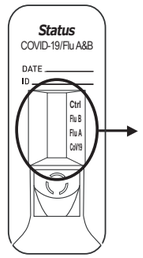
QUALITY CONTROL

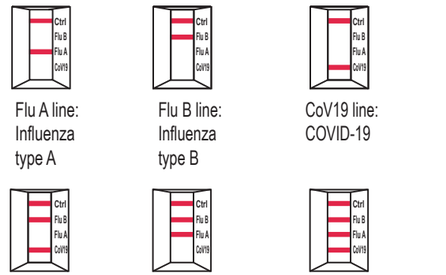
Internal Quality Control:
Each ***Status***™ **COVID-19/Flu A&B** test device has built-in controls. The Control line at the Ctrl position acts as an internal positive procedural control; i.e., a proper amount of sample was used, sample was properly added to the Extraction Well, sample migrated properly, 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, Flu A and/or Flu B Line(s) with Ctrl Line is positive.



Flu A line: Influenza type A

Flu B line: Influenza type B

CoV19 line: COVID-19

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

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

Flu A & Flu B lines: Influenza type A & B*

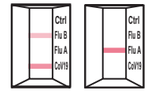
Flu A, Flu B & CoV19 lines: Influenza type A, B & COVID-19*

***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-teste with a new patient sample and new test kit. Repeatable "dual positive" results should be confirmed by an FDA-cleared molecular assay before reporting results.**

Ctrl Line only
Negative (–)

Negative Results are presumptive and may be confirmed with a molecular assay, if necessary, for patient management.

No Ctrl Line
Invalid



A reddish-purple colored line should always appear at the Control line (Ctrl) 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 sample and new test device.

Note: Positive test lines are usually very prominent but at times may vary in shade and intensity. A line of any intensity or thickness that appears in the Flu A, Flu B, or CoV19 region is considered a positive result. The intensity of the Control line should not be compared to that of the test line for the interpretation of the test result.
Take time to look at test lines very carefully. If you see a very light or faint test line appear, this is considered a POSITIVE result.

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).

SYMBOLS

Instructions for Use (Read)	Contains sufficient contents for 25 tests	CE Mark	Do not reuse.	EC REP	Authorized Representative
REF	Catalog Number	CONT	Contents	Manufacturer	LOT	Lot Number	VIA	Reagent Vial
2°C 30°C	Store at	DEV	Test Device	DIST	Distributed by	Expiration Date	Rx ONLY	For Prescription Use Only
SWAB	Swab	IFU	Instructions for Use	CONT +	Positive Control	MTD COVID-19/FLU	An in vitro immunochromatographic assay for the qualitative detection of SARS-CoV-2, influenza type A and type B antigens directly from nasal specimens
IVD	For in vitro Diagnostic Use	QRI	Quick Reference Instructions	CONT –	Negative Control		