

External Control

statID PRO™

COVID-19/Flu A&B

Instructions For Use

Carefully read the instructions before performing the test. Failure to follow the instructions may result in inaccurate test results.

IVD

R. Only

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783010	10 Positive swabs	10 Negative swabs	1 External Control Instructions for Use

INTENDED USE

The External Control – statID Pro COVID-19/Flu A&B is a ready-to-use external control kit for use with the statID Pro COVID-19/Flu A&B. This kit is designed to verify proper test procedure and performance of the statID Pro COVID-19/Flu A&B.

COMPOSITION

- The **positive control swabs** are composed of SARS-CoV-2, influenza A and influenza B recombinant antigens extract dried onto a swab, with a red shaft, containing 0.05% ProClin™ 300 as a preservative.
- The **negative control swabs** are composed of negative control buffer dried onto a swab, with a blue shaft, containing 0.05% ProClin™ 300 as a preservative.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- Do not use after the expiration date.
- Incompatibilities between this product and other manufacturer's test kits may occur.

- The swab should remain in the sealed pouch until use.
- The swab must be used within 2 hours of opening the sealed pouch.
- Follow Good Laboratory Practices. Wear protective clothing. Use disposal gloves.
- Do not eat, drink, or smoke in the area.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The control swab and test device should be discarded in a proper biohazard container after testing.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either refrigerated or at room temperature (2-30 C / 36-86 F). The swab is stable through the expiration date printed on the sealed pouch. The swab must remain in the sealed pouch until use. Do not freeze (below 0 C / 32 F).

MATERIALS REQUIRED BUT NOT PROVIDED

- Disposable gloves
- Timer, clock, or watch
- statID COVID-19/Flu A&B

TEST PROCEDURE

For the complete Test Procedure, refer to this section in the Instructions For Use of the statID COVID-19/Flu A&B.

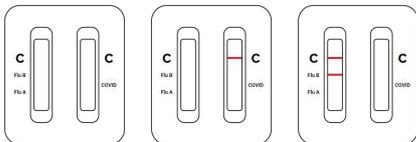
We recommend controls be run once for:

- Each new kit lot, each new operator, each new shipment, or as required by site quality control procedures and in accordance with local, state and federal regulations or accreditation requirements.

INTERPRETATION OF RESULTS

INVALID

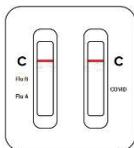
Missing 'C' line on
ONE or BOTH strips



If a control band (C) is **not visible in both result windows** (i.e. only **one** window displays the (C) line) after performing the test, **DO NOT CONTINUE** reading the results. The result is considered invalid.

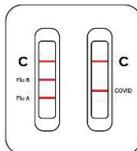
Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the test procedure and repeat the test using a new test device.

NEGATIVE



The presence of only **two** control lines (C), one in each result window, indicates a negative result. *This is the expected result for the negative control swab.*

POSITIVE



COVID-19/Flu A&B Positive: *This is the expected result for the positive control swab.*

The appearance of **five** lines:

Two control lines (C), one in each result window

One test line (Flu B)

One test line (Flu A)

One test line (COVID)

SYMBOL INDEX

	Do not reuse		See Instruction for Use		Expiration Date
	Tests per Kit		Store Between 2-30°F (36-86°C)		Keep Dry
	Batch Number		Catalog#		Keep Away from Sunlight
	Unique Device Identifier		For <i>in vitro</i> Diagnostic use only		Do not use if package is damaged
	Prescription Use Only		Negative control		Positive control

Manufactured For

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