meridian BIOSCIENCE®

statID PRO™

COVID-19/Flu A&B

QUICK REFERENCE INSTRUCTIONS (QRI)

For Professional Use
For *in vitro* diagnostic use

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

An anterior nasal swab sample can be self-collected by an individual aged 14 years or older. Children aged 2-13 years should be tested by an adult.

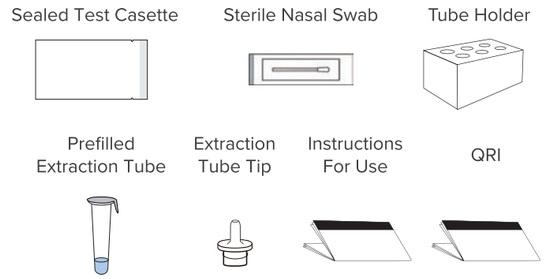
Do not use for testing children younger than 2 years of age.

WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION

- **Do not use the test if the patient has had symptoms for more than 5 days or no symptoms at all.**
- Do not use the test kit after its expiration date.
- Do not use the test if the pouch is damaged or open.
- Do not reuse the test cassette, processing solution, or swab.
- Do not open the test contents until ready for use. If the test cassette is open for an hour or longer, invalid test results may occur.
- When collecting a sample, only use the swab provided in the kit.
- Testing should be performed in an area with good lighting.
- **Keep the testing kit and kit components away from children and pets before and after use. Avoid contact with your 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 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.**

Hazard Category (mixture)	Hazard Class	GHS Hazard Statement for mixture	Hazardous Ingredients (%)*
2	Skin irritation	Causes skin irritation (H315)	Tris (2.4%) 1, 2-Benzisothiazolin-3-One (0.04%)
2	Eye irritation	Causes eye irritation (H320)	1, 2-Benzisothiazolin-3-One (0.04%) Tris (2.4%) Ethylenediamine ethoxylated propoxylated polymer (S9) (0.75%)

MATERIALS PROVIDED



Required but not provided: Timer or clock.

PREPARING FOR THE TEST

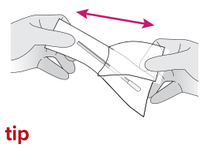
NOTE:
- Do not open the test contents until ready for use.

If the test cassette is open for an hour or longer, invalid test results may occur.
- Allow the test device and reagents to come to room temperature (15-30°C/59-86°F) prior to testing.

1. **Check the test's expiration date printed on the outer test packaging.**
2. Wash your hands with soap and water for 20 seconds and dry them thoroughly, or use hand sanitizer.
3. Remove the tube holder from the box.
4. Insert the extraction tube into the tube holder. Ensure that the tube is stable and upright.
5. Tear off the sealing film on the extraction tube gently to avoid spilling the liquid.
6. Remove test cassette from sealed pouch and lay it on a flat surface.

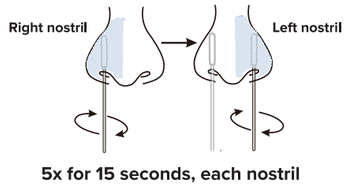
SAMPLE COLLECTION

1 Remove the swab from the pouch. Carefully insert the sterile swab no more than 3/4 inch (1.5 cm) into the nostril.



Be careful not to touch the swab tip (soft end) with hand.

2 Slowly rotate the swab **at least 5 times** against the nostril wall **for at least 15 seconds**. Remove the swab and repeat in the other nostril using the same swab.



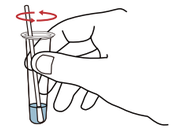
5x for 15 seconds, each nostril

SAMPLE COLLECTION (CONT'D)

Note: If you are swabbing others, please wear a face mask. With children, the maximum depth of insertion into the nostril may be less than ½ to ¾ of an inch, and you may require another adult to hold the child's head while swabbing.

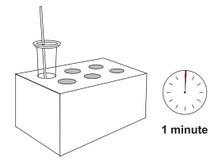
RUNNING THE TEST

3 Immerse the swab into the prefilled extraction tube and swirl the swab in the buffer. Ensure the sample is mixed thoroughly by **making at least 6 circles.**



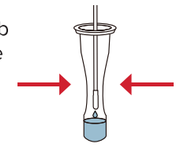
Sample must be mixed in the extraction buffer within 1 hour of sample collection.

4 Leave the swab in the extraction tube for **1 minute**. A timer is recommended for this step.

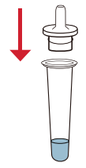


5 After 1 minute, pinch the tip of the swab from the outside of the tube to remove any excess sample in the swab.

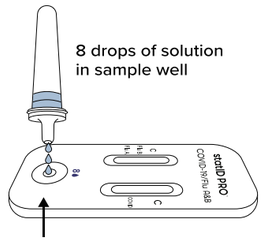
Remove and discard the swab.



6 Hold the tube upright and insert extraction tube tip into tube opening. Ensure a tight fit to prevent leaking.



7 Invert the extraction tube and **squeeze 8 drops** of test sample into the sample well. Then discard the tube.



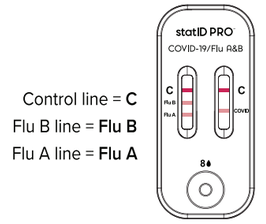
Sample must be applied to the test cassette within one hour of completing step 3.

8 Start timer. Read results at 15 minutes.

Do not interpret results before 15 minutes or after 20 minutes, as this may result in false or invalid results.

15 minutes

INTERPRETING YOUR RESULTS



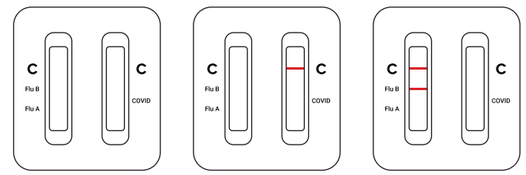
Control line = **C**
Flu B line = **Flu B**
Flu A line = **Flu A**

C = Control line
COVID = COVID-19 line

- Look for lines next to 'C' (Control), 'Flu B', 'Flu A' and 'COVID'.
- Look closely! Any faint line is still a line.
- For help in understanding the results, refer to Frequently Asked Questions at the end of this Result Interpretation section.

INVALID TEST RESULT

Missing 'C' line on ONE or BOTH strips



Check to see if a line is visible at the control line 'C' on both strips.

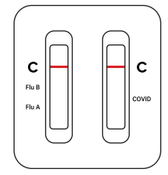
STOP

If a 'C' line is not seen, or only see one C line, DO NOT CONTINUE reading the results. The test is invalid.
Repeat the test with a new sample and new test kit materials.

Note: The 3 images displayed are examples only; additional invalid outcomes are possible.

NEGATIVE TEST RESULT

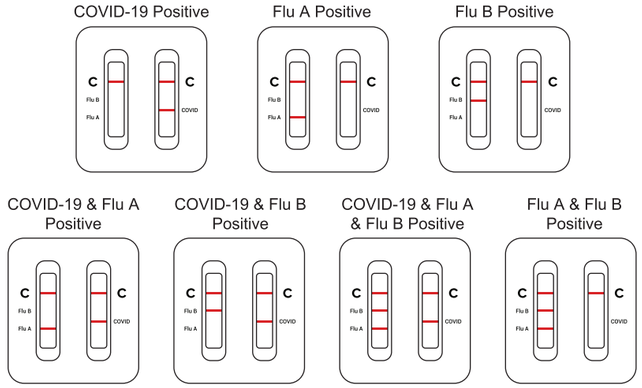
Both 'C' lines only



If a line is not seen at 'COVID', 'Flu A' or 'Flu B', these viruses were not detected in the sample.

POSITIVE TEST RESULT

Both 'C' lines must be PRESENT



If a line is seen at any one, or multiple, of the 'COVID', 'Flu A' or 'Flu B' areas, the test result is positive and the virus annotated next to the positive line was detected.

Additional Information: Reading Results

Scan QR code for more information on reading results.

Webpage: https://www.meridianbioscience.com

FREQUENTLY ASKED QUESTIONS

Q1: WHAT DOES AN INVALID TEST RESULT MEAN?
A: If the control line (C) is not visible on both test strips, the test is invalid, even if any test line is visible. An invalid test result means the test is unable to determine infection with influenza or SARS-CoV-2 (COVID) or not. The test needs to be repeated with a new kit and sample.

Q2: WHAT DOES A NEGATIVE RESULT MEAN?
A: A negative test result means COVID-19, Flu A, and/or Flu B viruses were not detected in the sample. A negative result is presumptive because despite a negative result the patient may still have COVID-19, Flu A, and/or Flu B infection. This is because the amount of virus in the sample may be too low for the test to detect, which is called a 'false negative result'. False negative results can occur if the test result is read before the 15 minutes have passed or when sample has only a low amount of virus in it. Low amount of virus can occur if the sample is taken at a time when symptoms just started appearing, or when the patient has already started to feel better at the end of the infection. There is a higher chance of false negative results with antigen tests compared to laboratory-based molecular tests. If the patient tested negative and continues to experience COVID-19, Flu A and/or Flu B-like symptoms, the patient should seek follow-up care with the healthcare provider.

Q3: WHAT DOES A POSITIVE RESULT MEAN?
A: A positive test result means that any one, or multiple, of the viruses detected by this test were also detected in the sample. In rare instances, individuals may also have co-infections with other bacteria or viruses that this test is not designed to detect. This means the virus detected by this test may not be the definitive or the only cause of disease. There is a very small chance this test can give a false positive result.

Q4: WHAT IF I AM UNCERTAIN HOW TO INTERPRET THE RESULTS?
A: If uncertain how to proceed, contact Technical Support Services at 1.800.343.3858 (8AM to 6PM, EST)

Q5: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?
A: There are different kinds of tests for the viruses that cause COVID-19 and the flu. Molecular tests detect genetic material from the virus. Antigen tests, such as the statID PRO™ COVID-19/Flu A&B Antigen Test, detect proteins from the virus. Due to the lower sensitivity of antigen tests, there is a higher chance this test may give a false negative result.

Q6: HOW ACCURATE IS THIS TEST?
A: The statID PRO™ COVID-19/Flu A&B Antigen Test was compared to an FDA-authorized known high sensitivity SARS-CoV-2 PCR test and an FDA-cleared known high sensitivity Influenza A and B PCR test. For more information on the performance of the test refer to the performance data in the Instructions for Use (IFU).

INTENDED USE

The statID PRO™ COVID-19/Flu A&B Antigen Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. This test is for use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older.

All negative results are presumptive and should be confirmed with an FDA-cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2, or other pathogens. Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough and/or shortness of breath, should therefore seek follow-up care from their healthcare provider.

Positive results do not rule out co-infection with other respiratory pathogens and therefore do not substitute for a visit to a healthcare provider or appropriate follow-up.

STORAGE AND STABILITY

- Store the test kit between 36-86 °F (2-30 °C) in a place out of direct sunlight.
- The unsealed cassette is valid for 1 hour. It is recommended to use the test kit immediately after opening. The expiration date is on the package.

LIMITATIONS

- The clinical performance of this test was established based on the evaluation of a limited number of clinical specimens collected between February 2024 through April 2024. The clinical performance has not been established for all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. There is a risk of false negative results due to the presence of novel, emerging respiratory virus variants. Test accuracy may change as new virus variants of COVID-19 and influenza emerge.
- A negative test result may occur if the level of antigen in the sample is below the detection limit of the test or if the sample is collected, handled or transported improperly.
- 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.
- False positive test results are more likely when the prevalence of SARS-CoV-2, Flu A/B is low in the community.
- Positive results do not rule out co-infection with other respiratory pathogens.
- 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.

LIMITATIONS (CONT'D)

- This device is a qualitative test and cannot provide information on the amount of virus present in the specimen.
- This test detects both viable (live) and non-viable influenza A, influenza B, and SARS-CoV-2. 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 sample.
- Exposure to cream lotion-based hand sanitizer, hand sanitizer with 80% ethanol and liquid gel hand soap may cause false negative results with this test.
- Individuals who recently received nasally administered influenza A or influenza B vaccine may have false positive influenza test results after vaccination.
- This test does not distinguish between SARS-CoV and SARS-CoV-2.

SYMBOLS

	Consult instructions for use	Σ	Tests per kit		Keep away from sunlight
IVD	For *in vitro* diagnostic use only		Use-by date (Expiration date)		Do not re-use
	Store at 36~86°F/2~30°C	LOT	Batch code	REF	Catalogue number
UDI	Unique device identifier		Keep dry		
	Do not use if package is damaged				

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