

CorDx Tyfast COVID-19 Ag Rapid Test

For *in vitro* diagnostic use.

- Children of 2-13 years old should be tested by an adult.
- These are not the full instructions for use.
- Please read the entire test procedure before performing this test.
- Refer to CorDx Tyfast COVID-19 Ag Rapid Test Product Insert for complete instructions.

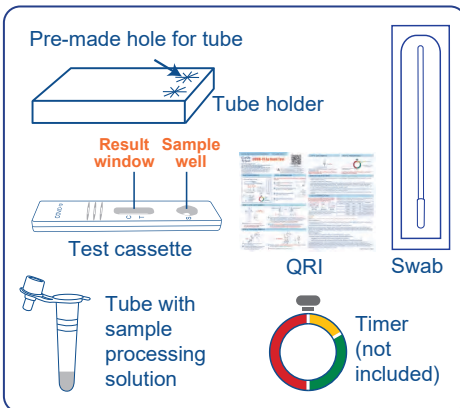


Scan for instructions and timer



A false result may occur if all the test steps are not followed as indicated below. If you skipped or incorrectly performed one or more steps, repeat the test with a new sample and cassette.

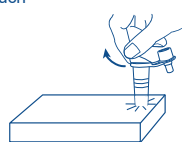
TEST COMPONENTS



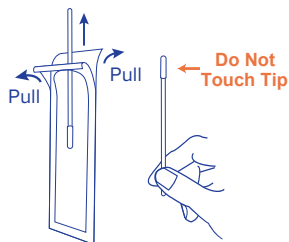
TEST PREPARATION

Note: Do not use if any of the test kit contents or packaging is damaged.

- Check the **Expiration Date** on the package. **Do not use an expired test kit!**
- Remove the test cassette from the pouch and place it on a clean, flat surface.
- Insert the tube in the pre-made hole on the back of the kit box.
- Remove the foil from the top of the tube.

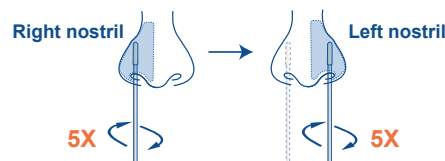


STEP 1: COLLECT SAMPLE



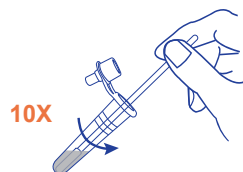
- Remove the swab from the pouch.

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



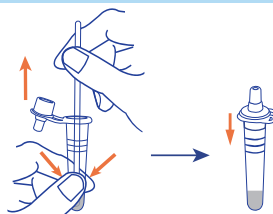
- Carefully insert the swab tip into one nostril about **1/2 to 3/4 inch**. Firmly and slowly rotate the swab 5 times, brushing against the inside walls of the nostril to ensure both mucus and cells are collected.
 - Do not push the swab further if you meet resistance.
 - For young children, do not insert more than **1/2 inch**.
- Using the **same swab**, repeat this process for the other nostril to ensure an adequate sample is collected from both nostrils. **Note: Failure to swab properly may cause incorrect results.**

STEP 2: PROCESS SAMPLE



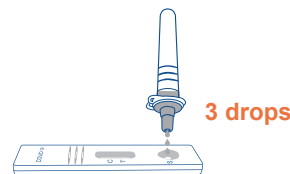
- Insert the swab into the tube until it touches the bottom.
- Rotate the swab at least 10 times while pressing the swab head against the bottom and side of the tube.

Squeeze



- Remove the swab **while squeezing the sides of the tube** to express as much liquid as possible from the swab.
- Attach the dropper tip firmly onto the tube.

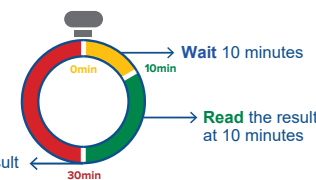
STEP 3: ADD SAMPLE



Gently squeeze the tube and dispense 3 drops of solution into the sample well.

Note: Invalid results can occur if less than 3 drops are added to the Sample Well.

STEP 4: READ RESULT



Do not read the result after 30 minutes

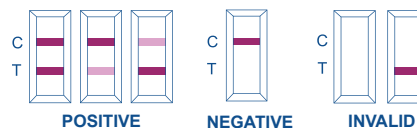
Note: False results can occur if the test is read before 10 minutes or after 30 minutes.

HOW TO USE THIS TEST

- An anterior nasal swab sample can be self-collected by an individual aged 14 years and older. Children aged 2 to 13 years should be tested by an adult.
- Do not use on anyone under 2 years of age.
- Serial testing should be performed in all individuals with negative results; individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours. Individuals without symptoms of COVID-19, and with initial negative results, should be tested again after 48 hours and, if the 2nd test is also negative, a 3rd time after an additional 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.
- If you test negative but continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19. However, you should follow up with your healthcare provider.
- If your test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.

TEST INTERPRETATION

Note: If you are prescribed eye-glasses or contact lenses for vision correction, you must wear them when performing and interpreting the test.



Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Invalid

If the Control (C) line is not visible, the test is invalid. Re-test with a new swab and new test device.

COVID-19 Positive (+)

If the Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible colored test (T) line with the control line (C) should be read as positive.

You do not need to perform repeat testing if you have a positive result at any time.

A positive test result means that the virus that causes COVID-19 was detected in your sample and it is very likely you have COVID-19 and are contagious. Please contact your doctor/primary care physician or your local health authority immediately and 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).

COVID-19 Negative (-)

If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.

To increase the chance that the negative result for COVID-19 is accurate, you should:

- Test again in 48 hours if you have symptoms on the first day of testing.
- Test 2 more times at least 48 hours apart if you do not have symptoms on the first day of testing.

A negative test result indicates that the virus that causes COVID-19 was not detected in your sample. A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR. If you test negative and continue to experience COVID-19-like symptoms, (e.g., fever, cough, and/or shortness of breath) you should seek follow up care with your health care provider.

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results for COVID-19.

Status on first day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 3	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

INTENDED USE

The CorDx Tyfast COVID- 19 Ag Rapid Test is a visually read lateral flow immunoassay device intended for the rapid, qualitative detection of SARS-CoV-2 virus nucleocapsid protein antigen directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19.

This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older.

The CorDx Tyfast COVID- 19 Ag Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.

All negative results are presumptive. Symptomatic individuals with an initial negative test result must be re-tested once between 48 and 72 hours after the first test using an antigen test or a molecular test for SARS-CoV-2. Negative results do not preclude SARS-CoV-2 infections or other pathogens and should not be used as the sole basis for treatment. Positive results do not rule out co-infection with other respiratory pathogens.

This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision. Individuals who test negative and experience continued or worsening COVID-19 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider.

The performance characteristics for SARS-CoV-2 were established from September, 2023, to December, 2023, when SARS-CoV-2 Omicron was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.

WARNINGS, PRECAUTIONS AND SAFETY INFORMATION

- **Do not use this test when you have symptoms for more than 5 days or if you have no symptoms.**
- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- If you skipped or incorrectly performed one or more steps, repeat the test with a new sample and cassette.
- This product is only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- 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.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- Test components are single-use. Do not re-use.
- Once opened, the test card should be used within 60 minutes.
- If uncertain how to proceed, contact Technical Assistance at Support@CorDx.com.
- When collecting an anterior nasal swab sample, only use the swab provided in the kit.
- Inadequate or inappropriate specimen collection, may yield false negative test results.
- Testing should be performed in an area with good lighting.
- If you are prescribed eye-glasses or contact lenses for vision correction, you must wear them when performing and interpreting the test.
- Dispose of all materials in household waste.
- For the most up-to-date information on COVID-19, please visit: www.cdc.gov/COVID-19
- Keep the test kit and kit components away from children and pets before and after use. Avoid contact with your 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.poissonhelp.org> or 1-800-222-1222.

Chemical	Harms (GHS Code) for each ingredient	Concentrations
Triton X-100	Harmful if swallowed (H302) Causes skin irritation (H315) Causes serious eye damage (H318)	0.50%
ProClin 300	Harmful if swallowed (H302) Causes severe burns and eyedamage (H314) May cause an allergic skin reaction (H317)	0.05%
EDTA-Na ₂ ·2H ₂ O	Harmful if swallowed (H302) May cause damage to organs (Respiratory Tract) through prolonged or repeated exposure if inhaled (H373)	0.50%

IMPORTANT

Do not use this test as the only guide to manage your illness. Consult your healthcare provider if your symptoms persist or become more severe.

Individuals should provide all results obtained with this product to their healthcare provider.

KIT STORAGE AND STABILITY

Storage: store at 36~86°F/2~30°C in a place out of direct sunlight and out of reach of children.

Reagents and devices must be used at room temperature (59~86°F/15~30°C). The unsealed cassette is valid for 1 hour. It is recommended to use the testing kit immediately after opening. The expiration date is printed on the package.

LIMITATIONS

- 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.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between March 2022 and May 2022. 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. 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.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. If you continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with a healthcare provider.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and you likely have COVID-19.
- 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.

FREQUENTLY ASKED QUESTIONS

1) WHAT ARE THE KNOWN AND POTENTIAL RISKS AND BENEFITS OF THE TEST?

Potential risks include: a) Possible discomfort during sample collection. b) Possible incorrect test result (see Warnings and Test Interpretation sections for more information).

Potential benefits include: a) The results, along with other information, can help you and your healthcare provider make informed recommendations about your care. b) The results of this test may help limit the potential spread of COVID-19 to your family and others in your community.

2) WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?

There are different kinds of tests for the SARS-CoV-2 virus that causes COVID-19. Molecular tests detect genetic material from the virus. Antigen tests, such as the CorDx Tyfast COVID-19 Ag Rapid Test, detect proteins from the virus. Due to the lower sensitivity of antigen tests, there is a higher chance this test will give you a false negative result when you have COVID-19 than a molecular test would.

3) HOW ACCURATE IS THIS TEST?

Clinical studies have shown that antigen tests more accurately determine whether you are infected with the virus that causes COVID-19 when taken multiple times across several days. Repeat testing improves test accuracy. This serial testing approach is recommended to minimize the risk of incorrect results. For more information on the performance of the test and how the performance may apply to you, please refer to the performance data in the Healthcare Provider Instructions for Use (IFU).

4) WHAT IF I HAVE A POSITIVE TEST RESULT?

A positive result means that it is very likely you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. You should self-isolate from others and contact a healthcare provider for medical advice about your positive result.



5) WHAT IF I HAVE A NEGATIVE TEST RESULT?

A negative test result indicates that antigens from the virus that causes COVID-19 were not detected in your sample. However, if you have symptoms of COVID-19, and your first test is negative, you should test again in 48 hours since antigen tests are not as sensitive as molecular tests. If you do not have symptoms and received a negative result, you should test at least two more times with 48 hours in between tests for a total of three tests. If you have a negative result, it does not rule out SARS-CoV-2 infection; you may still be infected and you may still infect others. It is important that you work with your healthcare provider to help you understand the next steps you should take.

6) WHAT DOES AN INVALID TEST RESULT MEAN?

An invalid result means the test was not able to tell if you have COVID-19 or not. If the test is invalid, a new swab should be used to collect a new nasal specimen and you should test again with a new test.

INDEX OF SYMBOLS

	Do not re-use		Caution		Consult instructions for use
	Catalogue number		Manufacturer		Keep dry
	Store at 36~86°F/2~30°C		Keep away from sunlight		In vitro diagnostic medical device
	Do not use if package is damaged and consult instructions for use				

TECHNICAL SUPPORT

For technical support, please email Support@CorDx.com or contact +1-800-711-5355.