

CoviDx™ SARS-CoV-2 Rapid Antigen Test

Quick Reference Instructions

For In Vitro Diagnostic Use Only

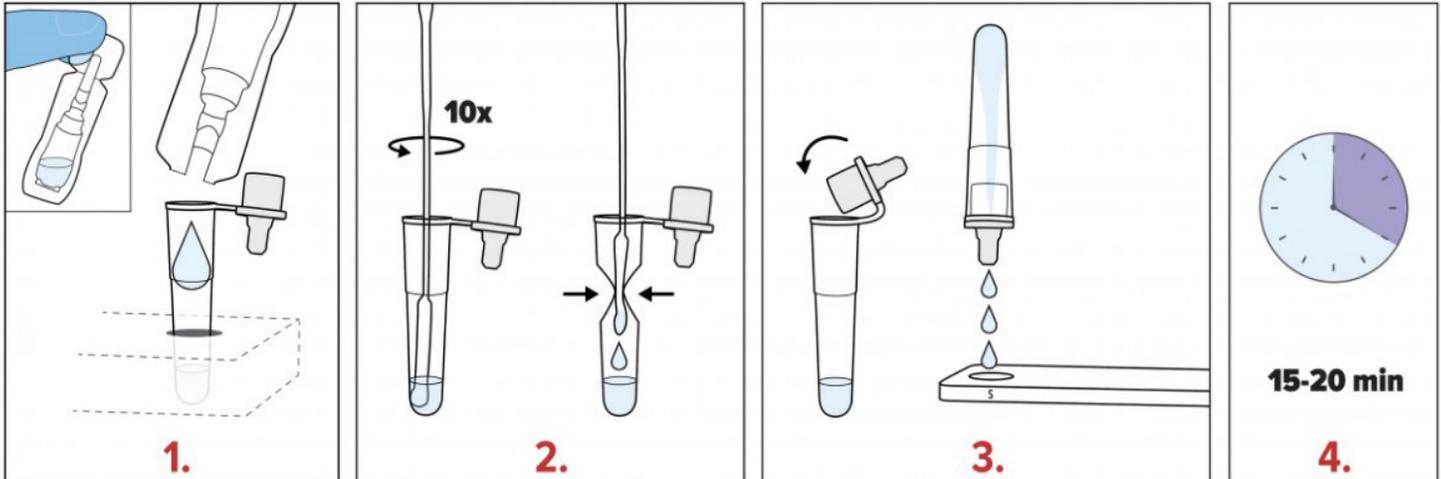
Review the full procedure, including recommended Quality Control (QC) procedures, before performing the test. This is not a complete Package Insert. Check the expiration date on all packaging. Nasal or nasopharyngeal swab samples should be collected by a trained healthcare provider. Use standard precautions for collecting and handling a nasal or nasopharyngeal swab sample. Allow all reagents and samples to reach room temperature before testing (15-30°C/59-86°F). Remove the test from the foil pouch just before testing and place on a flat surface.

Nasal Swab Sample Collection

Gently hold and tilt the patient's head with one hand. Carefully insert the swab into the left nostril and gently rotate the swab, ensuring that the swab tip is inserted about 2 cm (<1 inch) into the nostril until resistance is met at the turbinates. Slowly rotate the swab in a circular path against the nasal wall. Be sure to collect any nasal drainage that may be present on the swab. Gently remove the swab and carefully insert the same swab into the right nostril repeating the collection procedure.

Nasopharyngeal Swab Sample Collection

Gently hold the patient's head with one hand, carefully insert the swab into the nostril, and slowly enter deep along the bottom of the lower nasal passage. When the top of the swab reaches the back wall of the nasopharyngeal cavity, gently rotate and then slowly remove the swab.



Place an extraction tube in the cardboard workstation. Tear off top of extraction reagent vial and **empty the entire contents** into the extraction tube.

Add the swab to the extraction tube. Rotate the swab approximately **10 times**, pressing the swab head against the extraction tube. Squeeze the swab head against the extraction tube to retain as much of the liquid as possible, then remove and discard swab. Immediately proceed to step 3.

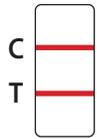
Place cap on extraction tube, invert the extraction tube, and add **4 drops** vertically to the sample well of the test device.

Read the test results at 20 minutes. Positive results can be read as early as 15 minutes. Do not read after 30 minutes.

NOTES:

Dispose in the proper biohazard receptacle. After testing, remove gloves, clean hands, and wear a new pair of clean gloves before testing each patient.

Reading CoviDx™ Test Results



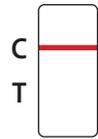
Positive

Positive Result

A red line appears in both the test line region 'T' and the control line region 'C'.

A Positive result indicates the presence of SARS-CoV-2 antigen in the sample.

Even if the test line is weak or incomplete it should be interpreted as a positive result. Weak lines may be caused if the antigen concentration is low.

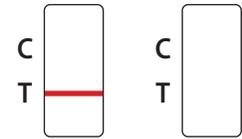


Negative

Negative Result

A red line appears in the control line region 'C' only. No line appears in the test line region 'T'.

A Negative result indicates the absence of SARS-CoV-2 antigen in the sample, or the concentration is below the limit of detection of the test.



Invalid

Invalid Result

A control line fails to appear. Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

After Obtaining Your Results

If the first test is **negative**, repeat the test after 24 hours. If the second test is negative, do one more test after another 24 hours.

- o If you are already self-isolating (quarantining) because of an exposure (i.e. close contact or travel), a negative test does not change the self-isolation duration.
- o If you are isolating because of symptoms but have no known exposure, you can stop self-isolating once you have two negative test results and are symptom-free.

If the test is **positive**, continue self-isolating and follow current public health guidelines.

CoviDx™

