**RAPID COVID-19 ANTIGEN SELF-TEST**

**CLINITEST®**

**PREP**

Do not use if test is expired.

GATHER MATERIALS

- Wash your hands with soap and water for 30 seconds or use hand sanitizer.
- **TEST DEVICE**:
  - Tube
  - Sterile swab with plastic stick end
  - Timer
  - Timers for 1 minute and 15 minutes
  - TUBE TIP pouches

**UNPACK**

- Find tube holder shown on the back of the box. Push tube through outndex hole.

**STEP 1. PLACE TUBE IN TUBE HOLDER**

Find tube holder shown on the back of the box. Push tube through outndex hole.

**STEP 2. OPEN TUBE**

Remove the seal from the tube. Avoid spilling the liquid.

**STEP 3. SWAB BOTH NOSTRILS**

Carefully insert swab tips into one nostril about 1/2 to 3/4 of an inch deep. Do not insert the swab any further if you feel any resistance. Rub the insides of the nostril in a complete circle at least 5 times. Make sure that protein from the swab inside the tube.

- Place the tube back into the tube holder. Keep the swab inside of the tube.
- Place the swab pouch in the same orientation as the swab was removed.

**STEP 4. OPEN SWAB**

Open the swab pouch on the end opposite the swab tip by peeling back the pouch cover. Hold the plastic stick end of the swab and remove from pouch. Be careful not to touch the tip of the swab.

**STEP 5. ADD 4 DROPS**

Hold the tube straight up and down above the test device and gently squeeze to add 4 drops of solution into the sample well, labeled as "S" on the test device.

**STEP 6. START TIMER**

Start timer for 15 minutes. Do not move the test device. Keep on a flat surface.

**STEP 7. READ TEST RESULT**

After 15 minutes first result window, labeled as "C" (for Control) and "T" (for Test) on the test device. It is important to record your test result at 15-20 minutes. False negative or false positive results can still occur. Test results are read before 15 minutes or after 30 minutes. Below are examples for positive, negative and invalid test results. Used test materials should be thrown away as household waste.

**COVID-19 POSITIVE**

If the test device looks like the example below, then protein from the virus that causes COVID-19 was detected— the sample. The test is positive if there are two pink/red lines present, one at the Control "C" line and one at the Test "T" line. Look very closely for line next to "T". This line can be very faint. Any faint pinkish "T" line is a positive result when the "C" line is also present.

**COVID-19 NEGATIVE**

If the test device looks like the example below then protein from the virus that causes COVID-19 was not detected. You will only see one line next to "C" and there will not be any line visible next to "T".

**IF THE TEST IS INVALID**

If at 15 minutes the line next to the "C" does not appear, even if any shade of detecting a "T" appears, the test result is invalid. If the test result is invalid, a new swab should be collected, and the test should be performed again with a new tube and test device.

**IF THE TEST IS POSITIVE**

A positive test result means that the virus that causes COVID-19 was detected in your sample. If you have COVID-19, it is important to be under the care of a healthcare provider. It is likely you will be asked to isolate yourself at home to avoid spreading the virus to others. There is a very small chance that this test can give a positive result that is incorrect (a false positive). If you test positive but do not have COVID-19. This means you could possibly still have COVID-19 even though the test is negative. If you test negative and continue to experience COVID-19-like symptoms of fever, cough and/or shortness of breath, you should seek follow-up care with your healthcare provider. Your healthcare provider will consider the test result with all other aspects of your history such as symptoms and exposures to decide how to care for you. For example, your healthcare provider may suggest you need another test to determine if you have the virus causing COVID-19. It is important you work with your healthcare provider to help you understand the next steps you should take. If you DO NOT have COVID-19 symptoms and your result is negative, you should test again with at least 24 hours and no more than 48 hours between tests. If both your first and second test results are negative, you may not have COVID-19.

**IF THE TEST IS NEGATIVE**

A negative test result means that protein from the virus that causes COVID-19 was not detected in your sample. If you took this test while you have symptoms, a negative test result usually means that your current illness was not caused by COVID-19. However, it is possible for this test to give a negative result that is incorrect (a false negative) in some people with COVID-19. Negative results do not rule out COVID-19. This means you could possibly still have COVID-19 even though the test is negative. If you test negative and continue to experience COVID-19-like symptoms of fever, cough and/or shortness of breath, you should seek follow-up care with your healthcare provider. Your healthcare provider will consider the test result with all other aspects of your history such as symptoms and exposures to decide how to care for you. For example, your healthcare provider may suggest you need another test to determine if you have the virus causing COVID-19. It is important you work with your healthcare provider to help you understand the next steps you should take. If you DO NOT have COVID-19 symptoms and your result is negative, you should test again with at least 24 hours and no more than 48 hours between tests. If both your first and second test results are negative, you may not have COVID-19.

**IF THE TEST IS INVALID**

If at 15 minutes the line next to the "C" does not appear, even if any shade of detecting a "T" appears, the test result is invalid. If the test result is invalid, a new swab should be collected, and the test should be performed again with a new tube and test device.

**RESULT**

If the test result is negative you may not have COVID-19.

**NOTE**

- If you are unable to complete the test, please call your healthcare provider.
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**RESULT**

If the test result is negative you may not have COVID-19.

**NOTE**

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**RESULT**

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**Chemical Name/CAS**

<table>
<thead>
<tr>
<th>Sodium Acetate</th>
<th>Acute Test 2 (Oval), HISO</th>
</tr>
</thead>
<tbody>
<tr>
<td>077-14-9</td>
<td>0.02% (devia)</td>
</tr>
<tr>
<td></td>
<td>and 0.00% (devia)</td>
</tr>
</tbody>
</table>

**Serial Testing Information and Limitations**

- If you have symptoms of COVID-19 that started within the last 7 days, you can use a single test.
- Testing for asymptomatic individuals should be performed at least twice over three days, with at least 24 hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.
- For serial testing, if your first test result is negative, you should test again with a new test in 24 to 48 hours.
- If your second test is positive, then please note that the test results that have COVID-19 have been found in your sample and you likely have COVID-19.
- If both your first and second tests are negative, you may not have COVID-19, however, you should follow up with your healthcare provider if you are at high risk for COVID-19.

**Frequently Asked Questions**

**Q: WHAT IS COVID-19?**

COVID-19 is an acute respiratory infectious disease caused by the SARS-CoV-2 virus, a novel Betacoronavirus. SARS-CoV-2 is mostly spread person-to-person, both by close contact with an infected person and by infected particles that can remain in the air for long periods of time. This can cause symptoms in some people, but many people with SARS-CoV-2 infection have no symptoms or have mild symptoms and might not realize they have the virus.

**Q: WHAT DOASYANTIGENTESTSANDMOLECULARTESTSMEAN?**

Antigen tests, such as the CLINITEST® Rapid COVID-19 Antigen Self-Test, detect proteins from the virus. Antigen tests are very specific for the SARS-CoV-2 virus but are not as sensitive as molecular tests. This means that a positive result is highly indicative of COVID-19, whereas a negative result does not rule out SARS-CoV-2 infection. If you anticoagulation may be used as an aid to the clinical diagnosis of a current COVID-19 infection. Do not use this test as the only guide to manage your illness. Please consult your healthcare provider if your symptoms persist or become more severe, or if you are allergic to any of the test's ingredients.

**Important**

- This test is intended to be used as an aid in the clinical diagnosis of a current COVID-19 infection. Do not use this test as the only guide to manage your illness. Please consult your healthcare provider if your symptoms persist or become more severe, or if you are allergic to any of the test's ingredients.

- Individuals should provide all results obtained with this product to their healthcare provider for public health reporting. All healthcare providers will report all test results they receive from individuals using the authorized product to relevant authorities. Your healthcare provider will work with you to determine how best to care for you based on your test result(s) along with your medical history, and your symptoms.

- Information on COVID-19, please visit: www.cdc.gov/COVID19

- For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-and-response/coronavirus/emergency-use-authorizations-euas

- For FDA Emergency Use Authorization (EUA) Only

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**Warnings, Precautions, and Safety Information**

- Read the CLINITEST® Rapid COVID-19 Antigen Self-Test Package Insert carefully before performing a test. Failure to follow directions may result in incorrect test results.
- Follow these directions carefully.
- The Test is intended to aid in the diagnosis of a current COVID-19 infection. Please consult a healthcare professional to discuss your results and any additional testing is required. You should wear a face mask if the test is done on the same day or at the time of the test. Children aged 2 to 13 years of age should be tested by an adult. The control line may show up before the test line, but it should not be visible. Do not use any test kits or packaging that is damaged or open. Test components are sensitive to light. Make sure there is sufficient light when testing. For best results, test in a well-lit area.
- Do not use nasal swabs containing preservatives that may affect the test results. Remove any preservatives from the nose before starting the test. Do not use any test kits or packaging that is damaged or open. Test components are sensitive to light. Make sure there is sufficient light when testing. For best results, test in a well-lit area.
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