QUICK REFERENCE INSTRUCTIONS

CLINITEST® diagnostic use only.
In vitro authorization is revoked sooner.
diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and
viruses or pathogens. The emergency use of this product is only authorized for
authorized only for the detection of proteins from SARS-CoV-2, not for any other
In the USA, this product has not been FDA cleared or approved; but has been

WASH HANDS
Wash your hands with soap and water for 30 seconds or use hand sanitizer.

GATHER MATERIALS
Check expiration date of the test kit before use. Expiration date is printed on the

STEP 1. PLACE TUBE IN TUBE HOLDER
Find tube holder shown on the back of the box. Push tube through outlined hole.

STEP 2. OPEN TUBE
Remove the seal from the tube. Avoid spilling the liquid. Make sure the tube is standing up straight.

STEP 3. OPEN SWAB
Open the swab pouch on the end opposite the plastic stick end. Take the swab out of the swab and remove from pouch. Be careful not to touch the tip of the swab.

STEP 4. PLACE SWAB IN TUBE
Remove the swab from the swab pouch. Immedately take the tube out of the tube holder and insert swab into the top of the tube vigorously by rolling the swab for at least 6 circles. Make sure there is a tight fit.

STEP 5. OPEN TEST DEVICE
Open the test device by tearing the area shown below. Place the test device on a flat surface.

STEP 6. READ TEST RESULT
After 15 minutes (Expected result window), take a close look at the “C” (for Control) and “T” (for Test) windows.

TEST DEVICE POUCH

TUBE
TUBE HOLDER
STORAGE TUBE

TIP:
Remember to do Step 1 only if you are ready to begin the test.

TUBE
TUBE HOLDER
TIP:

TEST DEVICE POUCH

TUBE
TUBE HOLDER
STORAGE TUBE
Read the CLINITEST® Rapid COVID-19 Antigen Test Package Insert carefully before performing a test. Failure to follow directions may produce inaccurate test results.

Follow directions for use:
- 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 required.
- Keep test kit and materials out of reach of children and pets before and after use.
- You should wear a face mask if masking is required.
- This test is read visually. Use of repaired or damaged test strips may damage the test result.
- Do not open test kit contents until ready to use. If the cassette is orange for an hour or longer, invalid test results may occur.
- Do not use the test after the expiration date shown on the test cassette package.
- Do not use any of the test kit contents if packaging is damaged or open.
- Filter components are single use only.
- Make sure there is sufficient light when testing. For best results, read test in a well-lit area.
- Do not use nasal swabs for at least 30 minutes before collecting a nasal sample.
- Remove any piercings from the nose before starting the test.
- Do not open the test kit unless you are ready to use. If the cassette is orange for an hour or longer, invalid test results may occur.
- Do not use the test after the expiration date shown on the test cassette package.
- Do not use any of the test kit contents if packaging is damaged or open.
- Filter components are single use only.

Q: WHAT IS COVID-19?
A: 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, by both individuals with symptoms and those who are asymptomatic or presymptomatic. SARS-CoV-2 is one of many coronaviruses that cause respiratory infections, and it may not be the only cause of disease.

Q: WHAT ARE THE POTENTIAL RISKS OF THIS TEST?
A: Possible incorrect test results (see Result Interpretation section).

Q: WHAT IF YOU TEST POSITIVE?
A: COVID-19 infection can cause COVID-19 disease. Individuals who test positive with CLINITEST® Rapid COVID-19 Antigen Self-Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

Q: WHAT IF YOU TEST NEGATIVE?
A: If your first or second test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.

Q: WHAT IS SERIAL TESTING?
A: Serial testing is when one person tests themselves multiple times for COVID-19 on a routine basis, such as every day or every other day. By testing more frequently, you may detect COVID-19 more quickly and reduce spread of infection. Serial testing is most useful in settings where many people are at risk of having COVID-19, such as in settings with continuous or close contact with COVID-19, especially when you do not have any symptoms.

Q: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?
A: There are many kinds of tests for the virus that causes COVID-19. Molecular tests detect genetic material from the virus. Antigen tests, such as the CLINITEST® Rapid COVID-19 Antigen Test, detect proteins from the virus. Antigen tests are very sensitive for the SARS-CoV-2 virus but are not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection. If your test result is negative, you should discuss with your healthcare provider whether an additional test is necessary and if you should continue isolating at home. There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19.

Q: IS THE TEST ACCURATE?
A: The CLINITEST® Rapid COVID-19 Antigen Test is intended for non-prescription sale and use, as applicable, for an adult lay user testing another aged 2 years or older. The CLINITEST® Rapid COVID-19 Antigen Test is for use only under the Food and Drug Administration’s Emergency Use Authorization.

Q: WHAT IF YOU TEST NEGATIVE?
A: A negative test result indicates that antigens from the virus that causes COVID-19 were not found in your sample. If you have symptoms, you likely do not have COVID-19. If you do not have symptoms and you receive a negative result, then you are likely not infected with COVID-19. However, not all COVID-19 infections result in symptoms causing the virus to spread. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. For example, you may be a false negative result if you do not perform the test correctly or if the level of antigen from the virus is causing COVID-19 is below the test limits. The amount of antigen in a sample may decrease the longer you have symptoms of infection. If you test negative and continue to experience symptoms of fever, cough and/or shortness of breath you should seek care with your healthcare provider. Your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, recent exposures, available, and geographic location of places you have recently traveled) in deciding how to care for you. Your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19.

Q: WHAT IS COVID-19?
A: 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, by both individuals with symptoms and those who are asymptomatic or presymptomatic. It is important that you work with your healthcare provider to help you understand the next steps you should take.

The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of these tests.

Q: WHAT DOES AN INVALID TEST RESULT MEAN?
A: The test result is invalid (even if test line shows up). An invalid result means the test was not able to tell you 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 the test should be run again, using a new test tube and kit.

Q: WHAT IS SERIAL TESTING?
A: Serial testing is when one person tests themselves multiple times for COVID-19 on a routine basis, such as every day or every other day. By testing more frequently, you may detect COVID-19 more quickly and reduce spread of infection. Serial testing is most useful in settings where many people are at risk of having COVID-19, especially when you do not have any symptoms. 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.

Q: WHAT IS THE CLINITEST® RAPID COVID-19 ANTIGEN SELF-TEST?
A: This CLINITEST® Rapid COVID-19 Antigen Test is a lateral flow chromatographic immunoassay intended for the qualitative detection of nucleoprotein antigen from SARS-CoV-2. This test is authorized for non-prescription home use with self-collected anterior nasal swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first 7 days of symptoms onset. This test is also authorized for non-prescription home use with self-collected anterior nasal (nasal) swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

In vitro performance has been established with COVID-19 positive sera and live SARS-CoV-2 virus. It is not intended for use in diagnostic laboratories for blood specimens. The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of these tests.

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of COVID-19, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposure to COVID-19 or residing in communities with low prevalence of infection.

Individuals who test negative and continue to experience COVID-like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care from their healthcare provider.

Individuals who provide all products obtained with this product to their healthcare provider for public health reporting. All healthcare providers will report all test results they receive from individuals who use the authorized product to the Centers for Disease Control and Prevention (CDC) under the Laboratory Identification (LID) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

Q: WHAT ARE THE POTENTIAL RISKS OF THIS TEST?
A: • Possible incorrect test results (see Result Interpretation section).

Q: WHAT ARE THE POTENTIAL RISKS AND BENEFITS OF THIS TEST?
A: Potential risks include:
• Possible incorrect test results (see Result Interpretation section).

Q: WHAT IS SERIAL TESTING?
A: Serial testing is when one person tests themselves multiple times for COVID-19 on a routine basis, such as every day or every other day. By testing more frequently, you may detect COVID-19 more quickly and reduce spread of infection. Serial testing is most useful in settings where many people are at risk of having COVID-19, especially when you do not have any symptoms. 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.

Q: What is the incubation period for COVID-19?