For Emergency Use Authorization (EUA) Only.

In vitro diagnostic use only.

In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product is authorized by the Department of Health and Human Services under Public Health Emergency Declaration Dated November 27, 2020. The authorized use is limited to in vitro diagnostic use.

14 years of age or older. If you have any questions about using the test or reading the results please call our customer care hotline.

Test results are positive if two pink/red lines are 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 visible pink/red "T" line is a positive result when the "C" line is also present. If the test device looks like the examples below then the test is INVALID. 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.

Removing the swab from the tube, squeeze swab tip several times from outside of the tube. Try to release as much liquid from the swab as possible. Dispose the swab in the trash.

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

STERILE SWAB
(Not included)

If at 15 minutes the line next to the "C" does not appear, even if any visible pink/red "T" line is present, 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 you are swabbing others, please wear a face mask. With very young children, you may need another person to steady the child and you may not need to insert the swab as far into the nostril. For very young children, you may need another person to steady the child and you might need to rub the insides of the nostril. Take approximately 15 seconds to collect the specimen. Be sure to collect any nasal drainage that may be present on the swab. Remove swab from the nostril and repeat in your other nostril.

If you have any questions about using the test or reading the results please call our customer care hotline.

Telephone: 1-833-833-2340
E-Mail: customer.siemens-healthineers.com
www.clinitest.siemens-healthineers.com/us

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".

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If the test result is negative 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 device looks like the example below then protein from the virus that causes COVID-19 was detected. The example shows a test result that is positive (a false positive). If you test positive with the CLINITEST® COVID-19 Antigen Self-Test you should self-isolate and seek follow-up care with your healthcare provider. Your healthcare provider will consider the test result with all other aspects of your health history such as symptoms and your exposure to decide how to care for you. It is important to 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 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 device looks like the example below then protein from the virus that causes COVID-19 was detected. The example shows a test result that is positive (true positive) if you have COVID-19. A positive test result means that the virus that causes COVID-19 was detected in your sample and that 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 with the CLINITEST® COVID-19 Antigen Self-Test you should self-isolate and seek follow-up care with your healthcare provider as additional testing may be necessary. Your healthcare provider will work with you to determine how best to care for you based on your test results along with medical history and your symptoms.

COVID-19 POSITIVE
If the test device looks like the example below then protein from the virus that causes COVID-19 was detected. The example shows a test result that is negative (true negative) if you do not have COVID-19. 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). Some people with COVID-19 do not have 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 health history such as symptoms and your exposure to decide how to care for you. If you do NOT have COVID-19 symptoms and your result is negative, you should test again 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.

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 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 device looks like the example below then protein from the virus that causes COVID-19 was detected. 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.
Q: WHAT IS COVID-19?
A: COVID-19 is an acute respiratory infection caused by the SARS-CoV-2 virus, a new betacoronavirus. SARS-CoV-2 is most spread person-to-person, but can also be spread by infected patients who are asymptomatic. Based on the current knowledge, the incubation period is 1 to 14 days, most typically 4-5 days. Symptoms include fever, muscle, fatigue, and cough. For a full list of symptoms, see: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.

Q: WILL THIS TEST HURT?
A: No, the nasal swab is not sharp, and it should not hurt. Sometimes the swab can feel slightly uncomfortable. If you feel pain, please stop the test and seek advice from your healthcare provider.

Q: WHAT ARE THE KNOWN POTENTIAL RISKS AND BENEFITS OF THIS TEST?
Potential risks include:
- Possible discomfort during sample collection.
- Possible incorrect test results (see Result Interpretation section).

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

Q: WHAT IS SERIAL TESTING?
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 more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.

Q: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?
There are many different 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 Self-Test, detect proteins from the virus. Antigen tests are more specific 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 your care 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. Table S1 compares the different characteristics of antigen tests and molecular tests.

Q: HOW ACCURATE IS THIS TEST?
A: A: An evaluation where results from the CLINITEST® Rapid COVID-19 Antigen Test were compared to FDA authorized molecular SARS-CoV-2 test, the CLINITEST® Rapid COVID-19 Antigen Home Test correctly identified 89.4% of positive specimens and 99.3% of negative specimens. The performance of this test is still being studied in patients without symptoms and signs of respiratory infection and for serial screening. Performance may differ in these populations.

Q: WHAT IF YOU TEST POSITIVE?
A: A positive antigen test result indicates that antigens from the virus that causes COVID-19 were found in your sample. If you have symptoms, you likely do have COVID-19. If you do not have symptoms and you receive a second negative result 24-48 hours after your first negative result, you then likely are not infected with COVID-19. However, negative results do not rule out SARS-CoV-2 infection.

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 potentially still have COVID-19 even though the test is negative. For example, you may receive a negative result if you did not perform the test correctly or if the level of antigen from the virus causing COVID-19 was below the limit of detection. The amount of antigen in a sample may decrease the longer you have symptoms or test negative and continue to experience symptoms of fever, cough and/or breathlessness that you should seek follow up care with your healthcare provider. Your healthcare provider will consider the test result together with all other information about your health (such as symptoms, possible exposures, and geographical 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.

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 the prevalent variants in circulation at the time and location of clinical evaluation. Performance at the time of testing may vary depending on the variant circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which over time.

Q: WHAT DOES AN INVALID TEST RESULT MEAN?
If no control line shows up on the test, the result is invalid (even if a test line shows up). 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 the test should be done again, using a new test kit.

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 at the only guide to manage your illness. Please consult your healthcare provider if your symptoms persist or become more severe, or if you are uncertain of the need to test.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting. Individuals should provide all results obtained with this product to their healthcare provider for public health reporting. All results should be provided to healthcare providers in accordance with local, state, and federal requirements using appropriate LPON and SNOCODE, as defined by the Laboratory in Vivo Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by Healgen.

The CLINITEST® Rapid COVID-19 Antigen Test is intended for non-prescription use, as well as, for an adult user testing another aged 2 years or older. The CLINITEST® Rapid COVID-19 Antigen Test is not for use under the Food and Drug Administration’s Emergency Use Authorization.

Warnings, Precautions, and Safety Information
Read the CLINITEST® Rapid COVID-19 Antigen Test Package Insert carefully before performing a test. Failure to follow directions may result in a false result.
- 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 is required.
- Keep test kit and materials in their original packaging until testing is performed.
- You should wear a face mask if enabling others.
- This test is not usually performed on children. ISH and can be performed on individuals aged 2 years or older.
- Children aged 2 to 13 years of age should be tested by an adult.
- The control line may show up without you touching the test cassette.
- Do not use any components after their expiration date.
- Do not open the test kit contents until ready to use. If the test cassette is open 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 or packaging is damaged or open.
- Test components are single use only.
- Make sure there is sufficient light when testing. For best results, test in a well-lit area.
- Do not use nasal swabs more than once with the same nasal sample.
- Remove any premises from the nose before starting the test.
- Do not use on anyone who is prone to nosebleeds or has had facial injuries or head injuries in the past six months.
- Do not use for repeat nasal swab testing on the same nasal sample.
- Do not offload the swab tip (specimen collection area) when handling the swab.
- The test is intended to be read at 15 minutes or later. Any line that appears after 30 minutes, false-negative or false-positive results may occur, and the test should be repeated with a new test cassette.
- Do not ingest any kit components.
- Avoid exposure of your eyes, mouth, or nose to the solution in the tube.
- The solution in the tube and the tube contains an ingredient that is hazardous to skin and eyes (see table below).
- If contact with the body occurs, rinse with water. If irritation persists, seek medical advice.

Chemical Name/CAS  |  GHS Code for applicable chemical  |  Concentration
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Sodium Acetate 26682-22-8 |  | 0.02% (v/v) and 0.05% (w/v)
Tris 9002-91-1 |  | 1.5%