concentric
by GINKGO

Information for Guardians of Test Takers Younger than 18 Years of Age

Everybody's health is connected.

Through their enrollment or affiliation with an organization, your student may access Concentric by Ginkgo, the COVID-19 testing service offered by Ginkgo Bioworks. To provide you information about this service, this document contains several sets of materials. There are no actions required by these texts; they are for your reference.

A separate document that includes the necessary consents, authorizations, notices, and terms of use will be sent to you for you to sign before your student is able to access the Concentric service. Please refer to that document for further information.

Important information about the Concentric by Ginkgo service can be found on the following pages:

Information for Test Takers and Frequently Asked Questions

Information for Test Takers

There are many causes of fever, cough, and shortness of breath. COVID-19 is just one condition that may cause these symptoms. This test does not rule out the possibility of other illnesses and infections that may be present instead of or in addition to COVID-19.

If you feel like you are having a medical emergency, please call 9-1-1. You should contact your healthcare provider if your symptoms get worse or you experience any new symptoms. If you are experiencing trouble breathing, persistent pain or pressure in your chest, new confusion, inability to wake or stay awake, bluish lips or face, or any other symptoms that are severe or concerning to you, please seek immediate medical care.

Information for Test Takers 18 Years of Age or Older

What is Concentric by Ginkgo's COVID-19 PCR test?
Ginkgo Bioworks, Inc. ("Ginkgo") has engaged Rutgers, The State University of New Jersey, acting through RUCDR Infinite Biologics ("Rutgers") to allow us to provide access to The Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay performed in the Rutgers Clinical Genomics Laboratory, a CLIA-certified high complexity laboratory (the "Rutgers Test").

The version of the Rutgers Test offered by Concentric by Ginkgo is a saliva-based test.

The Rutgers Test being offered by Concentric by Ginkgo is a PCR (polymerase chain reaction)-based test that is designed to detect the virus that causes COVID-19 in respiratory specimens, for example nasal, oral swabs, or saliva.

A PCR (polymerase chain reaction) test checks for genetic material (viral RNA) produced by the virus. This is used to detect the presence of the virus that causes COVID-19.

Is this test FDA-approved or cleared?
No. This test is not yet approved or cleared by the United States FDA. When there are no FDA-approved or cleared tests available, and other criteria are met, FDA can make tests available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA for this test is supported by the Secretary of Health and Human Services (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics for the detection and/or diagnosis of the virus that causes COVID-19.

This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration that circumstances exist justifying emergency use of In Vitro Diagnostics (IVDs) for the detection and/or diagnosis of COVID-19, unless it is sooner terminated or revoked (after which the test may no longer be used).

This test has been authorized by FDA under an EUA for use by authorized laboratories.

This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.

Who should get tested?
The Center for Disease Control (CDC) indicates (as of July 2, 2020 update) that there are five populations for which SARS-CoV-2 testing with viral tests (i.e., nucleic acid or antigen tests) is appropriate:

- Individuals with signs or symptoms consistent with COVID-19
- Asymptomatic individuals with recent known or suspected exposure to SARS-CoV-2 to control transmission
- Asymptomatic individuals without known or suspected exposure to SARS-CoV-2 for early identification in special settings
- Individuals being tested to determine resolution of infection (i.e., test-based strategy for Discontinuation of Transmission-based Precautions, HCP Return to Work, and Discontinuation of Home Isolation)
- Individuals being tested for purposes of public health surveillance for SARS-CoV-2

Generally, viral testing for SARS-CoV-2 is considered to be diagnostic when conducted among individuals with symptoms consistent with COVID-19 or among asymptomatic individuals with known or suspected recent exposure to SARS-CoV-2 to control transmission, or to determine resolution of infection. Viral testing is screening when conducted among asymptomatic individuals without known or suspected exposure to SARS-CoV-2 for early identification, and surveillance when conducted among asymptomatic individuals to detect transmission hot spots or characterize disease trends. To learn more, visit: https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html

How does the test work?

Prior to testing, authorization from a physician is required. This process is enabled by our platform.

After an organization enrolls, its members are invited to sign in to our portal and fill out a health questionnaire. Healthcare providers are provided by PWNHealth, who will evaluate your questionnaire responses and determine who is eligible for testing. PWNHealth is an independent healthcare provider network that provides oversight services and has partnered with Concentric's platform provider, ixLayer.

Eligible individuals can then proceed to the designated Test Center at a specified time in order to collect their sample.

Samples are shipped to our partner laboratory at Rutgers Clinical Genomics Laboratory, and results are communicated back to the individuals and organizations through our portal powered by ixLayer (who provides this portal in compliance with all applicable privacy laws and individual authorization).

What will my COVID-19 PCR test results tell me?

A PCR test can be used to detect the virus that causes COVID-19 on the day of sample collection. If your results are positive, it is important to limit your exposure to other people and continue to monitor your symptoms. If your results are negative, the test did not detect the presence of the virus that causes COVID-19 in the sample you provided.

For more information on positive and negative results associated with the Rutgers Test, please see the **patient fact sheet**.

After receiving your results, you will have an opportunity to speak with a licensed physician from our healthcare provider network partner, PWNHealth, who can answer any questions you may have about your test results and help determine next steps in care.

Depending on your test results, PWNHealth's Care Coordination Team may attempt to contact you to notify you of your results and schedule a telehealth consult with a physician or other healthcare provider.

What are the known and potential risks and benefits of the test?
Potential risks include:

- Possible incorrect test results. For more information, please see the below FAQ section "How to interpret the results."

Potential benefits include:

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

How do I prepare for the test?
You should NOT eat, drink, smoke, or chew gum for 30 minutes before giving your saliva sample.

You do not need to do anything to prepare for the test. You do not need to fast or stop taking any medications before testing. Further instructions will be provided to you at the lab or in your test kit.

Where can I get more information?
We encourage you to consult our FAQ or contact us at **support@concentricbyginkgo.com**.

Information for Test Takers Younger than 18 Years of Age

If your child's condition changes before you are able to obtain the test or the test result, please contact your pediatrician or visit your local emergency room as soon as possible.

Can my child get tested?
Testing is available for children 4 years of age and older. If your child has new or worsening **emergency warning signs**, such as severe trouble breathing, pain or pressure in the chest, feeling confused or having difficulty waking up, or blue-colored lips or face, call 911 or seek emergency medical attention instead of ordering this test.

Should my child get a COVID-19 PCR test?
A healthcare provider may order for your child to be tested if the healthcare provider believes your child may have been exposed to the virus that causes COVID-19 based on signs and symptoms (e.g., fever, cough, or difficulty breathing). A healthcare provider may determine that your child should get tested if:

- They have symptoms of COVID-19
- They live in or visit a place where people reside, meet, or gather in close proximity. This can include homeless shelters, group homes, detention centers, playgroups, schools, church, camp, daycare, etc.
- They have been in close contact with someone with confirmed COVID-19 within the past 14 days

This test may also be helpful if:

- Your child may have been exposed and has an underlying condition that may increase the risk for severe disease

If you have any other questions, we recommend that you speak with your child's primary healthcare provider about testing recommendations to see if testing is right for your child at this time.

How do I prepare my child for testing?

- It is important to set realistic expectations. Do not pretend the testing experience will be stress free. Reassure your child that the testing process will be quick and that you'll be with them the entire time. After the test, praise and comfort your child as needed.
- Make sure your child is tested when they are less likely to be tired or hungry. The test requires that your child should not eat, drink, smoke, or chew gum for 30 minutes before giving their saliva sample; however, your child does not need to fast or stop taking any medications before testing for longer than the required 30 minutes. Eating and drinking plenty of water before the 30 minute refraining period will help lower the risk of lightheadedness and can help make the process smoother.
- Talk about feelings or practice calming techniques before the test. You can do this by making a game of staying still or practicing breathing exercises with your child. It may also be helpful to distract your child during the procedure.
- Before testing, discuss any concerns and questions with your child's primary healthcare provider. Further instructions will be provided to you at the lab or in your test kit.

Where can I get more information?

- Centers for Disease Control and Prevention: Caring for Children
- World Health Organization: COVID-19 Resources for Care for Young Children

Please note:

The molecular test have not been cleared or approved by the Food and Drug Administration (FDA). The molecular test has been authorized by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories. This test has been authorized only for detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. This test is only authorized for the duration of the public health emergency for detection and/or diagnosis of COVID-19, unless the authorization is terminated or revoked sooner.

Frequently Asked Questions?

About the Test

What is COVID-19?
COVID-19 is caused by the SARS-CoV-2 virus. The virus, which can cause mild to severe respiratory illness, was first identified in Wuhan, China, and has now spread globally, including the United States. There is limited information available to characterize the spectrum of clinical illness associated with COVID-19 but it likely spreads to others when a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.).

What test am I being offered by Concentric by Ginkgo
Ginkgo Bioworks, Inc. ("Ginkgo") has engaged Rutgers, The State University of New Jersey, acting through RUCDR Infinite Biologics ("Rutgers") to allow us to provide access to The Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay performed in the Rutgers Clinical Genomics Laboratory, a CLIA-certified high complexity laboratory (the "Rutgers Test").

What is the Rutgers Test offered by Concentric by Ginkgo?
The Rutgers Test is a PCR (polymerase chain reaction)-based test that is designed to detect the virus that causes COVID-19 in respiratory specimens, for example nasal, oral swabs, or saliva.

The version of the Rutgers Test offered by Concentric by Ginkgo is a saliva-based test.

Important information about the Rutgers Test can be found here:

- FDA EUA Letter
- Rutgers EUA Summary
- FDA HCP Fact Sheet
- FDA Patient Fact Sheet

What is a COVID-19 PCR test?
A PCR (polymerase chain reaction) test checks for genetic material (viral RNA) produced by the virus. This is used to detect the presence of the virus that causes COVID-19.

How is a COVID-19 PCR test performed?
A PCR test is typically conducted either by a nasal swab, throat swab, or saliva collection. A nasal swab or throat swab test requires the insertion of a swab into your nose and/or the back of your throat. A saliva test requires providing a sample of your spit into a collection tube.

The version of the Rutgers Test offered by Concentric by Ginkgo is a saliva based test.

Is this test FDA-approved or cleared?
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This test has been authorized by FDA under an EUA for use by authorized laboratories.

This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.

When to Use the Test

Who is eligible to take the test?
An independent physician will determine whether to authorize your test request, if appropriate. This physician will be provided through PWNHealth. Before receiving a test, you will be asked to complete a short health questionnaire, which this physician will review.

Our healthcare provider network partner, PWNHealth, might deem certain individuals ineligible to take our test. In this case, PWNHealth will provide additional guidance, including what to do if the individual develops severe symptoms. Since advice given by PWNHealth is coming from an individual physician making medical recommendations, Concentric cannot vouch for advice given to you by a PWNHealth physician.

Who is PWNHealth?
PWNHealth is an independent healthcare provider network that provides oversight services to you in connection with the laboratory testing that you have requested. PWNHealth and its services are independent from the laboratory and company from whom you requested and registered for the test and their services.

In what states is the test authorized for use in?
The Rutgers Test is authorized for use across 50 states in the United States.

Who should get tested?
The Center for Disease Control (CDC) indicates (as of July 2, 2020 update) that there are five populations for which SARS-CoV-2 testing with viral tests (i.e., nucleic acid or antigen tests) is appropriate:

- Individuals with signs or symptoms consistent with COVID-19
- Asymptomatic individuals with recent known or suspected exposure to SARS-CoV-2 to control transmission
- Asymptomatic individuals without known or suspected exposure to SARS-CoV-2 for early identification in special settings

- Individuals being tested to determine resolution of infection (i.e., test-based strategy for Discontinuation of Transmission-based Precautions, HCP Return to Work, and Discontinuation of Home Isolation)
- Individuals being tested for purposes of public health surveillance for SARS-CoV-2

Generally, viral testing for SARS-CoV-2 is considered to be diagnostic when conducted among individuals with symptoms consistent with COVID-19 or among asymptomatic individuals with known or suspected recent exposure to SARS-CoV-2 to control transmission, or to determine resolution of infection. Viral testing is screening when conducted among asymptomatic individuals without known or suspected exposure to SARS-CoV-2 for early identification, and surveillance when conducted among asymptomatic individuals to detect transmission hot spots or characterize disease trends. To learn more, visit: **https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html**

Who is at highest risk of serious illness from COVID-19?

COVID-19 is a new disease and there is limited information regarding risk factors for severe disease. Based on currently available information and clinical expertise, **older adults and people with underlying medical conditions** are at higher risk for severe illness from COVID-19.

As you get older, **your risk for severe illness from COVID-19 increases**. For example, people in their 50s are at higher risk for severe illness than people in their 40s. Similarly, people in their 60s or 70s are, in general, at higher risk for severe illness than people in their 50s. The greatest risk for severe illness from COVID-19 is among those aged 85 or older.

People of any age with the **following conditions** are at increased risk of severe illness from COVID-19:

- Chronic kidney disease
- COPD (chronic obstructive pulmonary disease)
- Immunocompromised state (weakened immune system) from solid organ transplant
- Obesity (body mass index [BMI] of 30 or higher)

- Serious heart conditions, such as heart failure, coronary artery disease, or cardiomyopathies
- Sickle cell disease
- Type 2 diabetes mellitus

For more information visit:

- https://www.cdc.gov/coronavirus/2019-ncov/faq.html#Symptoms-&-Emergency-Warning-Signs
- https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/older-adults.html

How do I prepare for the test?
You should NOT eat, drink, smoke, or chew gum for 30 minutes before giving your saliva sample.

You do not need to do anything to prepare for the test. You do not need to fast or stop taking any medications before testing. Further instructions will be provided to you at the lab or in your test kit.

What are the known and potential risks and benefits of the test?
Potential risks include:

- Possible incorrect test results. For more information, please see the below FAQ section “How to interpret the results”.

Potential benefits include:

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

How to Interpret Results of the Test

What will my COVID-19 PCR test results tell me?
A PCR test can be used to detect the virus that causes COVID-19 on the day of sample collection. If your results are positive, it is important to limit your exposure to other people and continue to monitor your symptoms. If your results are negative, the test did not detect the presence of the virus that causes COVID-19 in the sample you provided.

For more information on positive and negative results associated with the Rutgers Test, please see the **patient fact sheet**.

After receiving your results, you will have an opportunity to speak with a licensed physician from our healthcare provider network partner, PWNHealth, who can answer any questions you may have about your test results and help determine next steps in care.

Depending on your test results, PWNHealth's Care Coordination Team may attempt to contact you to notify you of your results and schedule a telehealth consult with a physician or other healthcare provider.

What does it mean if I have a positive test result?
If you have a positive test result, it is very likely that you have COVID-19. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. There is a very small chance that this test can give a positive result that is wrong (a false-positive result). Your healthcare provider will work with you to determine how best to care for you based on the test results along with medical history, and your symptoms.

In the case of a positive result, a licensed physician from PWNHealth's Team will contact you to provide clinical guidance on the meaning of those results.

What does it mean if I have a negative test result?
A negative test result means that the virus that causes COVID-19 was not found in your sample. For COVID-19, a negative test result for a sample collected while a person has symptoms usually means that COVID-19 did not cause your recent illness.

However, 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. If this is the case, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

Where can I find any additional information on quarantine and isolation?
We recommend that you consult the **Coronavirus (COVID-19) Isolation / Quarantine Information PDF** provided by PWNHealth.

Are there any limitations to COVID-19 PCR tests?
For specific information about the limitations of the Rutgers Test, please refer to the **patient fact sheet**. You may also refer to the questions above, “What does it mean if I have a positive test result?” and “What does it mean if I have a negative test result?”.

A PCR test may not detect the virus in early stages of infection. In addition, a PCR test may not detect the virus if there was a problem with your sample, such as when the sample is not collected as directed. There is also the possibility of a false negative (a negative result that is incorrect) even if you’ve had recent exposure to the virus along with symptoms consistent with COVID-19.

Where can I get more information?

- Centers for Disease Control and Prevention: About Coronavirus Disease 2019 (COVID-19)
- World Health Organization: Coronavirus disease (COVID-19) outbreak
- PWNHealth: COVID-19 FAQs
- Centers for Disease Control and Prevention: Frequently Asked Questions
- Centers for Disease Control and Prevention: Overview of Testing for SARS-CoV-2
- Spectrum DNA collection device instructions
- FDA EUA Letter
- Rutgers EUA Summary
- FDA HCP Fact Sheet
- FDA Patient Fact sheet

What to Know About Children and COVID-19

What is the risk of my child getting sick from COVID-19?
Based on all available evidence, children do not have a higher risk of getting COVID-19 than adults. While some children and infants get sick with the virus, adults make up most of the known cases. Most cases in children occur due to exposure from someone in their household. Hospitalization is most common in children less than 1 year old and those with underlying conditions (such as lung diseases or moderate to severe asthma, heart complications, or weakened immune systems from cancer, medications, or transplants).

How do I protect my child from COVID-19?
You can protect your child from COVID-19 by encouraging them to take the same safety precautions as everyone else:

- Avoid close contact with people who are sick.
- Stay home when you are sick, unless you are seeking medical care.
- Clean and disinfect frequently touched objects and surfaces (including tables, doorknobs, light switches, countertops, handles, desks, phones, keyboards, toilets, faucets, and sinks).
- Launder items, including washable plush toys, using the warmest water setting allowed for the items. Dry them completely. Dirty laundry from an ill person can be washed with other people's items.
- Wash your hands often with soap and water for at least 20 seconds.
- Use an alcohol-based hand sanitizer with at least 60% alcohol if soap and water aren't available. Always wash hands with soap and water if your hands are visibly dirty.
- Avoid touching your eyes, nose, and mouth with unwashed hands.

Be sure to also track and follow community safety measures, such as school closures. Discourage children and teens from gathering in other public places while school is closed to help slow the spread of COVID-19 in the community.

Should children wear face masks?
The Centers for Disease Control and Prevention (CDC) recommends that every person aged 2 years and older wear a cloth covering or mask that covers their nose and mouth when they are out in public places. Cloth face coverings should NOT be put on babies or children younger than 2 because of the danger of suffocation. Wearing cloth face coverings is one safety measure that can help reduce the spread of COVID-19 when used in addition to other measures such as social distancing and frequent hand washing.

Should my child be around other children?
It is important that your child limits time with other children. If children meet in groups, it can put everyone at risk. Children can pass this virus to others who have an increased risk of severe illness from COVID-19. If children are playing outside their own homes, it is essential that they remain 6 feet from anyone who is not in their own household. For more information, visit the CDC website.

Should my child be around other people?
It is important that your child limits time with people who may be at high risk of severe illness from COVID-19. If others in your home have an increased risk, consider extra safety precautions to help separate your child from those people. Consider postponing visits or trips to see older family members and grandparents.

How do I talk to my child about COVID-19?
Outbreaks can be stressful for adults and children. Talk with your child about the outbreak and reassure them that they are safe. When you speak, try to remain calm. Explain to your child that most illnesses from COVID-19 seem to be mild. Children respond differently to stressful situations than adults. If you need support, The Centers for Disease Control and Prevention (CDC) offers resources to help talk with children about COVID-19.

Are COVID-19 symptoms different for children?
The symptoms of COVID-19 are similar in children and adults. However, children with the virus generally have mild symptoms and recover within one to two weeks. Symptoms in children include:

- Fever
- Cough
- Nasal congestion or runny nose
- Sore throat
- Shortness of breath
- Nausea or vomiting
- Diarrhea
- Tiredness
- Headache and muscle aches
- Refusing to eat or drink

There is more to be learned about how the disease impacts children. For example, it's not yet known whether some children may be at higher risk for severe illness, such as children with underlying medical conditions and special healthcare needs.

What should I do if my child has symptoms of COVID-19?
If your child develops symptoms of COVID-19, it is important to closely monitor them. Most people, including children, develop mild symptoms that resolve within two weeks. If your child develops symptoms of COVID-19, talk to your child's healthcare provider about steps you should take to help your child recover at home. The Centers for Disease Control and Prevention (CDC) recommends both children and adults follow the same steps if they have the virus. See those steps **here**. Notify your child's healthcare provider if someone else in your house becomes sick with COVID-19, so they can provide any advice specific for your child. If your child has new or worsening **emergency warning signs**, such as severe trouble breathing, pain or pressure in the chest, feeling confused or having difficulty waking up, or blue-colored lips or face, call 911. When you call, tell the operator you suspect your child has COVID-19 so that first responders can protect themselves and others.

What is multisystem inflammatory syndrome in children (MIS-C), and how is it related to COVID-19?

New evidence suggests that children who have or have had COVID-19 may later develop an inflammatory condition similar to Kawasaki disease or toxic shock syndrome. This condition is called **multisystem inflammatory syndrome in children (MIS-C)**. If you suspect that your child has symptoms of this inflammatory syndrome (fever, abdominal pain, vomiting, diarrhea, neck pain, rash, eye redness, or feeling overly tired), be sure to see your child's healthcare provider right away. The good news is that this condition is treatable when caught early.

Should my child get tested if they have symptoms of multisystem inflammatory syndrome in children (MIS-C)?

The Centers for Disease Control and Prevention (CDC) recommends that in individuals who have not been tested for COVID-19 and have symptoms of a condition that occurs after COVID-19 infection (like MIS-C), antibody testing may be used for further evaluation. Follow up with your child's healthcare provider for further information about testing related to MIS-C.

Information on the COVID-19 Molecular Test: FDA Emergency Use Authorization Summary

ACCELERATED EMERGENCY USE AUTHORIZATION (EUA) SUMMARY
SARS-CoV-2 ASSAY
(Rutgers Clinical Genomics Laboratory)

For in vitro diagnostic use
Rx only
For use under Emergency Use Authorization (EUA) Only

(The Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay will be performed in the Rutgers Clinical Genomics Laboratory, a Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a certified high-complexity laboratory, per the Instructions for Use that were reviewed by the FDA under this EUA).

INTENDED USE

The Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay is a real-time reverse transcription polymerase chain reaction (rRT-PCR) test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in oropharyngeal (throat) swab, nasopharyngeal swab, anterior nasal swab, mid-turbinate nasal swab, and bronchoalveolar lavage (BAL) fluid from individuals suspected of COVID-19 by their healthcare provider.

This test is also for use with saliva specimens that are self-collected at home or in a healthcare setting by individuals using the Spectrum Solutions LLC SDNA-1000 Saliva Collection Device when determined to be appropriate by a healthcare provider.

Testing is limited to Rutgers Clinical Genomics Laboratory (RCGL) at RUCDR Infinite Biologics – Rutgers University, Piscataway, NJ, that is a Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a certified high-complexity laboratory.

Results are for the detection and identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. Negative results for SARS-CoV-2 RNA from saliva should be confirmed by testing of an alternative specimen type if clinically indicated.

Testing with the COVID-19 RT-PCR test is intended for use by qualified clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures. The assay is intended for use under the Food and Drug Administration's Emergency Use Authorization.

Please refer to FDA's FAQs on Diagnostic Testing for SARS-CoV-2 for additional information regarding the collection appropriate specimen types for the detection of SARS-CoV-2.

DEVICE DESCRIPTION AND TEST PRINCIPLE

The Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay is a real-time reverse transcription polymerase chain reaction (rRT-PCR) test. The assay uses primers and probes that were developed and validated under the Emergency Use Authorization (EUA) for the TaqPath COVID-19 Combo Kit and are designed to detect RNA from SARS-CoV-2 in respiratory specimens from patients as recommended for testing by public health authority guidelines. The purpose of this EUA request is to enable testing of additional specimen types, including saliva, and use of alternative nucleic acid extraction and amplification systems available in the Rutgers Clinical Genomics Laboratory.

Anterior nasal swabs, mid-turbinate nasal swabs, oropharyngeal (throat) swabs and nasopharyngeal swabs and bronchoalveolar lavage fluid should be collected, transported and stored according to standard procedures. Saliva specimens must be collected, transported and stored using the Spectrum Solutions LLC SDNA-1000 Saliva Collection Device. Saliva specimens must be transported and stored at ambient temperature and tested within 56 hours of collection when stored at ambient temperature.

RNA extraction for all specimen types is performed using the PerkinElmer Chemagic 360 automated specimen processing system with the Chemagic Viral DNA/RNA 300 Kit H96. The input sample volume is 300µL, the elution volume is 50µL.

Reverse transcriptase-PCR (RT-PCR) is performed using the Applied Biosystems TaqPath COVID-19 Combo Kit with 5µL of the extracted sample.

INSTRUMENTS USED WITH THE TEST

The Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay is for use with the ThermoFisher Applied Biosystems QuantStudio 5 Real-Time PCR System equipped with software v1.3, or the Applied Biosystems ViiA7 Real-Time PCR System with the Applied Biosystems QuantStudio 5 software v1.3 for data analysis, and Perkin Elmer Chemagic 360 extraction instrument (software v6.3.0.3).

REAGENTS AND MATERIALS

Table 1. Reagents and materials required for use of the Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay

Reagent	Manufacturer	Catalogue #
Chemagic Viral DNA/RNA 300 Kit H96	PerkinElmer	CMG-1033-S
96 well Deep Well Plates	PerkinElmer	43001-0120
TaqPath COVID-19 Combo Kit	ThermoFisher Scientific	A147814
384 well PCR plate	ThermoFisher Scientific	4483273
Optical adhesive PCR plate cover	ThermoFisher Scientific	4311971
Nuclease-free water	--	--
Ethanol (96-100%)	--	--

CONTROLS

The controls supplied with the ThermoFisher - Applied Biosystems TaqPath COVID-19 Combo Kit are described in **Table 2**.

Table 2. Controls supplied with the Applied Biosystems TaqPath COVID-19 Combo Kit

Control Type	Purpose	Frequency of Testing
Negative	To monitor for cross-contamination during RNA extraction and RT-PCR	Once per batch of specimens
Positive	To monitor the integrity of the RT-PCR reagents and process	Once per run of RT-PCR
Internal (MS2 Phage)	To monitor the integrity of nucleic acid extraction and RT-PCR for each specimen	Added to each specimen and the Negative Control prior to extraction

In addition to these controls, a No Template Control containing none of the SARS-CoV-2 targets or the Internal Control is included in every PCR run. The results from the controls are interpreted according to the criteria shown in **Table 3**. If the results obtained with the Positive, Negative and No Template Controls do not meet the criteria shown, the results from the entire batch of samples are considered invalid and repeat testing must be performed.

Table 3. Ct values for controls that must be observed to obtain valid results

Control	Ct Value (Optical Channel)			
	N Gene (VIC)	S Gene (ABY)	ORF1ab (FAM)	MS2 Phage (JUN)
Negative	>40	>40	>40	≤37
Positive	<37	<37	<37	Undetermined [1]
No Template	Undetermined	Undetermined	Undetermined	Undetermined [1]
Internal	Any	Any	Any	<37

[1] The MS2 Phage Internal Control is not added to the Positive Control or No Template Control and no signal should be obtained

INTERPRETATION OF RESULTS

The results from testing of patient samples are interpreted according to the criteria described in **Table 4**.

Table 4. Result interpretation for patient samples

Ct Value (Optical Channel)				Result Interpretation
N Gene (VIC)	S Gene (ABY)	ORF1ab (FAM)	MS2 Phage (JUN)	
Undetermined	Undetermined	Undetermined	<37	Negative
Two of three <37			<37	Positive
One of three <37			<37	Re-test [1]
Undetermined	Undetermined	Undetermined	Undetermined	Re-test [1]

[1] Re-test required from the residual extracted sample and by processing a new aliquot of the original sample if volume permits; if the re-test result is the same as the original then report result as "inconclusive"

PERFORMANCE EVALUATION

1) Analytical Sensitivity

The LoD was determined using *in vitro* transcripts from Exact Diagnostics (SARS-CoV-2 Standard) that were diluted in SARS-CoV-2 negative nasopharyngeal swab matrix. An initial estimate of the LoD with the Applied Biosystems QuantStudio 5 Real-Time PCR System was obtained by testing three replicates at each of four different target levels: 1000, 500, 200 and 100 copies/mL. The lowest level at which all three replicates were positive for all three SARS-CoV-2 targets was 200 copies/mL. The estimated LoD was confirmed by testing an additional 20 replicates at the same target level. All 20 replicates produced the expected results for each SARS-CoV-2 target, and the LoD was therefore confirmed to be 200 copies/mL.

To validate use of the Applied Biosystems ViiA7 Real-Time PCR System for PCR amplification, an additional study was performed by testing 20 nasopharyngeal and 10 saliva samples that were each spiked with 400 copies/mL of the Exact Diagnostics SARS-CoV-2 transcripts. Positive results were obtained for each of the samples for all three target genes and the MS2 internal control, demonstrating that the ViiA7 Real-Time PCR system performed similarly to the QuantStudio 5. These results are acceptable.

2) Analytical Specificity

Inclusivity

The Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay is a modification of the previously authorized ThermoFisher Applied Biosystems TaqPath COVID-19 Combo Kit. The assay targets specific genomic regions of the SARS-CoV-2 nucleocapsid (N) gene, spike (S) gene, and ORF1ab region. Inclusivity was demonstrated under the original EUA by mapping the primers and probes to 185 complete SARS-CoV-2 genomes that were available in the GenBank and GISAID (Global Initiative on Sharing All Influenza Data) databases as of March 5, 2020. For all primers and probes, there was 100% homology to each of the SARS-CoV-2 sequences analyzed, with one exception; a single base mismatch (95.6% homology) with the reverse primer for ORF1ab in sequence EPI_ISL_407084

(BetaCoronavirus/Japan/AI/I-004/2020). The mismatch is located at the 5' end of the primer and is not expected to affect test performance

Cross-reactivity

The analytical specificity of the Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay was demonstrated *in silico* under the original EUA for the ThermoFisher Applied Biosystems TaqPath COVID-19 Combo Kit. The analysis included evaluation of the primer and probe homology with the 43 organisms and viruses listed in **Table 5**. Based on this analysis, significant amplification of non-target sequences that could result in cross-reaction (false-positive results) or interference (false-negative results) was considered unlikely to occur.

Table 5. Organisms and viruses evaluated for potential cross-reaction and/or interference with the Applied Biosystems TaqPath COVID-19 Combo Kit

Viruses	**Bacteria**
Adenovirus	*Bacillus anthracis*
Enterovirus	*Bordetella pertussis*
Human coronavirus 229E	*Chlamydophila pneumoniae*
Human coronavirus HKU1	*Chlamydophila psittaci*
Human coronavirus NL63	*Corynebacterium diphtheriae*
Human coronavirus OC43	*Coxiella burnetii*
Human Metapneumovirus (hMPV)	*Haemophilus influenzae*
Influenza A, B and C	*Legionella* (non-pneumophila)
MERS-coronavirus	*Legionella pneumophila*
Parainfluenza 1-4	*Leptospira* sp.
Parechovirus	*Moraxella catarrhalis*
Respiratory Syncytial Virus A and B	*Mycobacterium tuberculosis*
Rhinovirus/Enterovirus	*Mycoplasma pneumoniae*
SARS-coronavirus	*Neisseria elongata* and *Neisseria meningitidis*
Yeast/Fungus	*Pseudomonas aeruginosa*
Candida albicans	*Staphylococcus aureus*
Pneumocystis jirovecii	*Staphylococcus epidermidis*
	Streptococcus pneumoniae
	Streptococcus pyogenes
	Streptococcus salivarius

3) Clinical Evaluation

Nasopharyngeal Swabs

The performance of the Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay with nasopharyngeal swabs was evaluated using contrived specimens composed of leftover nasopharyngeal swab samples that were spiked with SARS-CoV-2 *in vitro* transcripts or human DNA (both Exact Diagnostics). A total of 30 contrived positive and contrived negative samples were tested. A summary of the results of the study is provided in **Tables 6** and **7**. All 30 (100%) contrived negative samples produced the expected results. Of the 30 contrived positive samples, all 30 (100%) produced positive results for

the N and S genes, whereas the ORF1ab target was positive for 25/30 samples (83.3%). No amplification of the ORF1ab target was observed with 1/10 samples (10.0%) at 200 copies/mL and 4/10 samples (40.0%) at 400 copies/mL. According to the result algorithm described in **Table 4**, above, a sample is considered positive for SARS-CoV-2 RNA if amplification is detected with at least two of the three SARS-CoV-2-specific target sequences. The results of the Clinical Evaluation with contrived nasopharyngeal swabs were therefore considered acceptable.

Table 6. Summary of results from the contrived specimen study with nasopharyngeal swabs, stratified by target level and measurand

Transcript Copies/mL	Number Tested	Analysis	Target (Optical Channel)			
			N Gene (VIC)	S Gene (ABY)	ORF1ab (FAM)	MS2 (JUN)
0	30	Positive (%)	0 (0)	0 (0)	0 (0)	0 (0)
		Mean Ct (SD)	N/A	N/A	N/A	24.4 (0.4)
200	10	Positive (%)	10 (100)	10 (100)	9 (100)	10 (100)
		Mean Ct (SD)	21.7 (4.3)	22.1 (6.0)	19.7 (1.6)	27.1 (1.2)
400	10	Positive (%)	10 (100)	10 (100)	6 (60.0)	10 (100)
		Mean Ct (SD)	27.0 (6.7)	26.6 (6.8)	21.1 (2.3)	26.1 (1.2)
600	4	Positive (%)	4 (100)	4 (100)	4 (100)	4 (100)
		Mean Ct (SD)	28.5 (5.2)	27.2 (4.5)	27.4 (6.2)	25.7 (0.9)
800	3	Positive (%)	3 (100)	3 (100)	3 (100)	3 (100)
		Mean Ct (SD)	33.0 (1.6)	30.5 (0.4)	35.0 (3.9)	25.0 (0.9)
1000	3	Positive (%)	3 (100)	3 (100)	3 (100)	3 (100)
		Mean Ct (SD)	28.8 (6.6)	27.7 (5.6)	29.0 (7.3)	25.8 (1.2)
All Positives	30	Positive (%)	30 (100)	30 (100)	25 (83.3)	30 (100)
		Mean Ct (SD)	26.2 (6.3)	25.7 (5.1)	24.2 (6.4)	26.2 (1.3)

N/A: Not applicable; SD: Standard Deviation

Table 7. Summary of positive and negative agreement with contrived nasopharyngeal swab specimens

		Contrived Specimen Type		
		Positive	**Negative**	**Total**
TaqPath SARS-CoV-2 Assay	**Positive**	30	0	**30**
	Negative	0	30	**30**
	Total	**30**	**30**	**60**
Positive Agreement		100% (30/30); 88.7-100% [1]		
Negative Agreement		100% (30/30); 88.7-100%		

[1] Two-sided 95% score confidence intervals

Saliva

A study was performed to evaluate the use of saliva as a specimen type for detection of SARS-CoV-2 in patients who are suspected of COVID-19. The study was conducted with symptomatic patients from three ambulatory care centers who were each provided with instructions for self-collection of saliva using the Spectrum Solutions LLC SDNA-1000 Saliva Collection Device. Self-collection of saliva samples was performed under the observation of a healthcare provider who subsequently (within 10 minutes) also collected either a nasopharyngeal or oropharyngeal swab from each patient for parallel testing for

SARS-CoV-2. The swabs were placed in viral transport medium for shipment to the testing laboratory. Both the saliva and swabs were transported at ambient temperature and tested using the Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay within 48 hours of collection. A summary of the results of the study is presented in **Tables 8** and **9**.

There was 100% positive and negative agreement between the results obtained from testing of saliva and those obtained from nasopharyngeal and oropharyngeal swabs. Overall mean Ct values were similar for saliva and either nasopharyngeal or oropharyngeal swabs, there was no correlation between Ct values from different samples from the same patient. Nevertheless, the results support the use of saliva as a specimen type for use with the Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay.

Table 8. Summary of qualitative results obtained from parallel testing of nasopharyngeal and oropharyngeal swab samples and saliva from patients suspected of COVID-19

		Nasopharyngeal Swab		
		Positive	**Negative**	**Total**
Saliva	**Positive**	26	0	**26**
	Negative	0	27	**27**
	Total	**26**	**27**	**53**
Positive Agreement		100% (26/26); 87.1-100% [1]		
Negative Agreement		100% (27/27); 87.5-100%		
		Oropharyngeal Swab		
		Positive	**Negative**	**Total**
Saliva	**Positive**	4	0	**4**
	Negative	0	3	**3**
	Total	**4**	**3**	**7**
Positive Agreement		100% (4/4); 51.0-100% [1]		
Negative Agreement		100% (3/3); 43.9-100%		
		Nasopharyngeal or Oropharyngeal Swab		
		Positive	**Negative**	**Total**
Saliva	**Positive**	30	0	**30**
	Negative	0	30	**30**
	Total	**30**	**30**	**60**
Positive Agreement		100% (30/30); 88.7-100% [1]		
Negative Agreement		100% (30/30); 88.7-100%		

[1] Two-sided 95% score confidence intervals

Table 9. Summary of results obtained from parallel testing of nasopharyngeal and oropharyngeal swab samples and saliva from patients suspected of COVID-19, stratified by measurand

Number of Patients	Sample Type	Analysis	Target (Optical Channel)			
			N Gene (VIC)	S Gene (ABY)	ORF1ab (FAM)	MS2 (JUN)
26 NP positive	NP swab	Positive (%)	26 (100)	26 (100)	26 (100)	26 (100)
		Mean Ct (SD)	24.4 (4.0)	24.5 (3.9)	23.6 (3.7)	24.3(2.6)
	Saliva	Positive (%)	26 (100)	26 (100)	26 (100)	26 (100)
		Mean Ct (SD)	23.5 (6.2)	24.6 (6.0)	23.6 (5.7)	26.0 (4.1)
27 NP negative	NP swab	Positive (%)	0 (0)	0 (0)	0 (0)	27 (100)
		Mean Ct (SD)	N/A	N/A	N/A	24.4 (1.2)
	Saliva	Positive (%)	0 (0)	0 (0)	0 (0)	27 (100)
		Mean Ct (SD)	N/A	N/A	N/A	25.0 (1.9)
4 OP positive	OP swab	Positive (%)	4 (100)	4 (100)	4 (100)	4 (100)
		Mean Ct (SD)	24.7 (4.0)	24.3 (3.9)	23.5 (4.4)	25.4 (1.8)
	Saliva	Positive (%)	4 (100)	4 (100)	4 (100)	4 (100)
		Mean Ct (SD)	22.0 (7.1)	22.3 (7.2)	21.4 (7.1)	29.6 (5.6)
3 OP negative	OP Swab	Positive (%)	0 (0)	0 (0)	0 (0)	23.5 (1.5)
		Mean Ct (SD)	N/A	N/A	N/A	3 (100)
	Saliva	Positive (%)	0 (0)	0 (0)	0 (0)	3 (100)
		Mean Ct (SD)	N/A	N/A	N/A	23.1 (1.4)

NP: Nasopharyngeal; OP: Oropharyngeal; N/A: Not applicable; SD: Standard Deviation

Clinical Confirmation

The first 5 positive and first 5 negative nasopharyngeal specimens as determined by Rutgers Clinical Genomic Laboratory using the Rutgers TaqPath SARS-CoV-2 Assay were also tested by the New Jersey State Health Department using the previously authorized CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel. There was 100% (5/5) positive and negative agreement for the specimens tested. These results are acceptable and support use of the by Rutgers Clinical Genomic Laboratory TaqPath SARS-CoV-2 Assay for testing clinical specimens.

4) Simulated Shipping Study with the SDNA-1000 Saliva Collection Device

To support home use of the Spectrum Solutions LLC SDNA-1000 Saliva Collection Device, a Simulated Shipping Study was performed that was designed to evaluate the effect of temperature variation on the stability of SARS-CoV-2 RNA during transport of saliva specimens. The study was conducted using residual clinical specimens that had previously been reported as SARS-CoV-2 positive or negative using the Rutgers TaqPath SARS-CoV-2 Assay, and which were stored at -80°C until the start of the study. The SARS-CoV-2 positive specimens were selected based on the Ct values obtained upon initial testing and covered the spectrum of Ct values observed with the assay.

To perform the study, the specimens were thawed and then subjected to the thermal profiles outlined in **Tables 10** and **11** which were intended to simulate the extreme temperature conditions that may be experienced in shipment of specimens during the summer and winter, respectively. At the conclusion of each thermal profile, the samples were retested with the Rutgers TaqPath SARS-CoV-2 Assay and the results obtained

were compared to those reported upon initial testing at the time the specimens were received. A summary of the mean Ct values observed for each SARS-CoV-2 specific target gene is provided in **Table 12**. The Ct values for each individual sample are presented graphically in **Figure 1**.

Nineteen out of 20 Low Positive samples (95%) and 10/10 High Positive samples were reported as positive after exposure to the summer and winter temperature excursions. The mean and standard deviation of the Ct values for each gene target were similar before and after simulated shipping, with no evidence of significant degradation of the SARS-CoV-2 RNA. All SARS-CoV-2 negative specimens were reported as "negative."

These results demonstrate that SARS-CoV-2 RNA positive saliva specimens are stable in the SDNA-1000 Saliva Collection Device when exposed to a broad range of temperature conditions. These data support the use of the SDNA-1000 Saliva Collection Device for transport and storage of specimens following home collection of saliva.

Table 10. Summer temperature excursion

Temperature (°C)	Cycle Period	Time (hours)	
		Cycle Period	Total Time [1]
40	1	8	8
22	2	4	12
30	3	2	14
22	4	36	50
40	5	6	56

[1] Sum of Cycle Periods

Table 11. Winter temperature excursion

Temperature (°C)	Cycle Period	Time (hours)	
		Cycle Period	Total Time [1]
-80	1	8	8
18	2	4	12
-10	3	4	16
4	4	38	56

[1] Sum of Cycle Periods

Table 12. Summary of results from the Simulated Shipping Study with the SDNA-1000 Saliva Collection Device

Sample Group	Test Point	N	Mean Ct (Standard Deviation)			Positive (%)
			N Gene	ORF1ab	S Gene	
Negative	T = 0	10	N/A	N/A	N/A	0 (0)
	Summer [1]	10	N/A	N/A	N/A	0 (0)
	Winter [2]	10	N/A	38.6 (--) [3]	N/A	0 (0)
Low Positive	T = 0	20	29.0 (1.9)	29.3 (2.1)	29.4 (3.1)	20 (100)
	Summer	20	29.9 (2.4)	29.3 (2.9)	29.0 (2.5)	19 (95)
	Winter	20	30.0 (2.4)	29.1 (2.7)	28.8 (2.0)	19 (95)
High Positive	T = 0	10	20.8 (2.2)	21.3 (1.9)	20.7 (2.7)	10 (100)
	Summer	10	23.5 (3.5)	22.3 (3.8)	22.5 (4.0)	10 (100)
	Winter	10	23.4 (3.3)	22.2 (3.4)	22.1 (3.2)	10 (100)

N/A: Not Applicable

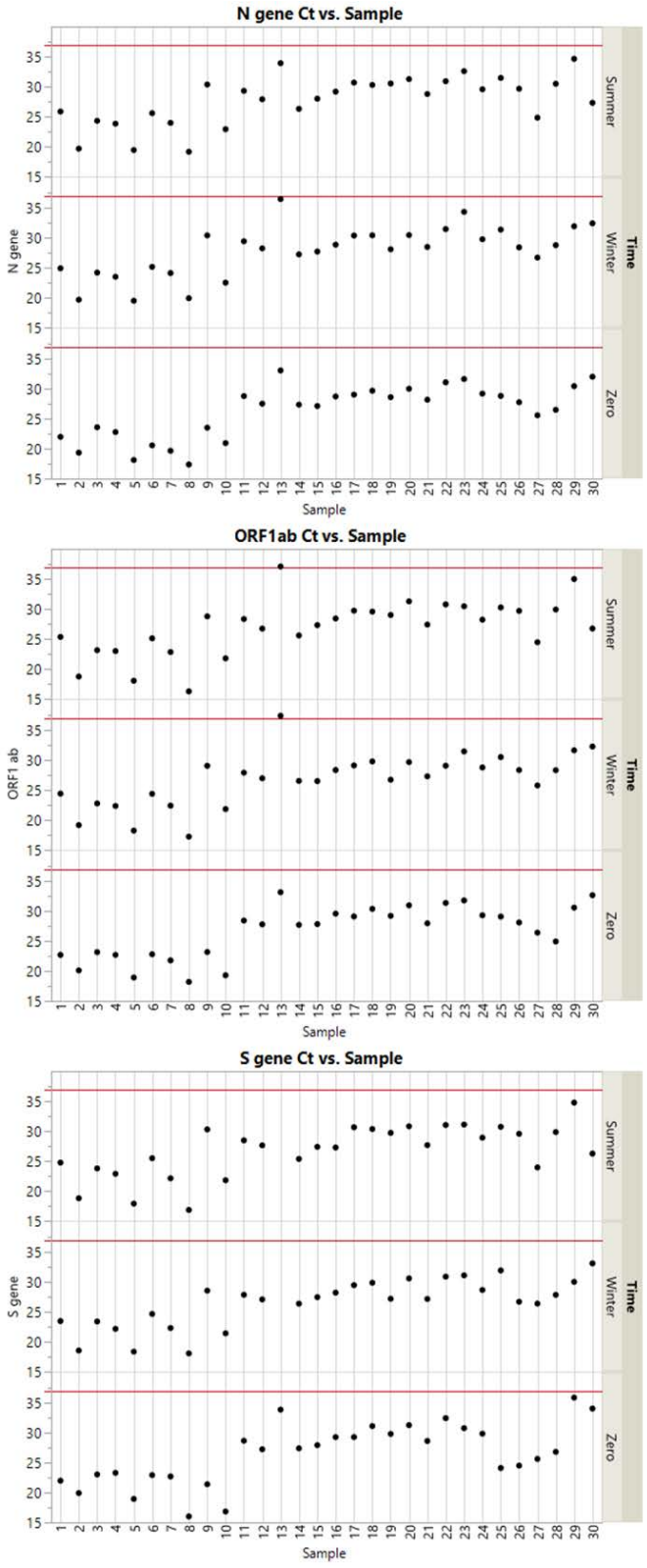
[1] Testing performed at the conclusion of the thermal excursions described in **Table 10**

[2] Testing performed at the conclusion of the thermal excursions described in **Table 11**

[3] 1 sample gave a Ct value for ORF1ab but no amplification was observed for the other two SARS-CoV-2 targets. Based on the algorithm used for the Rutgers TaqPath SARSCoV-2 Assay (**Table 4**), at least two targets must have Ct values <37 for a specimen to be called positive for SARS-CoV-2 RNA. Therefore, this sample was recorded as "SARS-CoV-2 RNA Negative."

[4] Low Positive: Ct >25 at T= 0 for all targets; High Positive: Ct <25 at T = 0 for all targets

Figure 1. Ct values for each SARS-CoV-2 target gene by sample



Samples 1-10: High Positive (Ct value <25 for each target at T = 0)
Samples 11-30: Low Positive (Ct value >25 for each target at T = 0)

LIMITATIONS

- Testing of saliva specimens is limited to patients with symptoms of COVID-19.

Information on the COVID-19 Molecular Test: FDA Fact Sheet for Patients

FACT SHEET FOR PATIENTS

Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay

Rutgers Clinical Genomics Laboratory **May 7, 2020**

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

- **For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage:**

- **https://www.cdc.gov/COVID19**

What is COVID-19?
COVID-19 is caused by the SARS-CoV-2 virus. The virus, which can cause mild to severe respiratory illness, was first identified in Wuhan, China, and has now spread globally, including the United States. There is limited information available to characterize the spectrum of clinical illness associated with COVID-19 but it likely spreads to others when a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.).

What is the Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay?
The test is designed to detect the virus that causes COVID-19 in respiratory specimens, for example nasal, oral swabs or salvia.

Why was my sample tested?
You were tested because your healthcare provider believes you may have been exposed to the virus that causes COVID-19 based on your signs and symptoms (e.g., fever, cough, difficulty breathing), and/or because:

- You live in or have recently traveled to a place where transmission of COVID-19 is known to occur, and/or
- You have been in close contact with an individual suspected of or confirmed to have COVID-19.

Testing of the samples will help find out if you may have COVID-19.

What are the known and potential risks and benefits of the test?

Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result (see below for more information).

Potential benefits include:

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

What does it mean if I have a positive test result?
If you have a positive test result, it is very likely that you have COVID-19. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to

- **Where can I go for updates and more information?** The most up-to-date information on COVID-19 is available at the CDC General webpage: **https://www.cdc.gov/COVID19.** In addition, please also contact your healthcare provider with any questions/concerns.

others. There is a very small chance that this test can give a positive result that is wrong (a false positive result). Your healthcare provider will work with you to determine how best to care for you based on the test results along with medical history, and your symptoms.

What does it mean if I have a negative test result?
A negative test result means that the virus that causes COVID-19 was not found in your sample. For COVID-19, a negative test result for a sample collected while a person has symptoms usually means that COVID-19 did not cause your recent illness.

However, 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. If this is the case, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

Is this test FDA-approved or cleared?
No. This test is not yet approved or cleared by the United States FDA. When there are no FDA-approved or cleared tests available, and other criteria are met, FDA can make tests available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA for this test is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics for the detection and/or diagnosis of the virus that causes COVID-19.

This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying emergency of IVDs, unless it is terminated or revoked by FDA (after which the test may no longer be used).

- **Where can I go for updates and more information?** The most up-to-date information on COVID-19 is available at the CDC General webpage: **https://www.cdc.gov/COVID19.** In addition, please also contact your healthcare provider with any questions/concerns.

Example of Health Questionnaire

Health History Pre-screening

Concentric by Ginkgo COVID-19 Test

Why are we asking these questions?

These questions help physicians learn more about your health for purposes of evaluating your test request.

Please answer the following.

First name | Last name

Sex

○ Male ○ Female

Date of birth

Month | Day | Year

Email address

Phone number

Address

City | State | Zip

COVID-19 Health screening questions

These questions were developed by PWNHealth and are used to guide health care provider decisions of whether and when to test individuals.

What is your ethnicity?

- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino
- ☐ Other
- ☐ Prefer not to answer

What is your race? (Choose one or more from the following racial groups)

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian and other Pacific Islander
- ☐ Two or more races
- ☐ White
- ☐ Other
- ☐ Prefer not answer

Do any of the following statements apply to you?

- **I am 65 years of age or older**
- **I have been told by my doctor that I am very overweight or obese**
- **I have a chronic condition (e.g. diabetes, high blood pressure, kidney disease or on dialysis, liver disease, lung disease or asthma, etc.)**
- **I have a heart condition (e.g. previous heart attacks, heart failure, etc.)**
- **I have a neurologic condition that affects my ability to cough (e.g., had a stroke)**
- **I am pregnant**
- **I regularly use tobacco or nicotine products (e.g. cigarettes, e-cigarettes, vapes, hookah, etc.)**
- **I have a condition that weakens my immune system or makes it harder to fight infections (e.g. AIDS, cancer, lupus, rheumatoid arthritis, solid organ or bone marrow transplant, etc.)**
- **I am taking medication that weakens my immune system (e.g. steroids, chemotherapy, immunologics, etc.)**

○ Yes

○ No

Please select the statement that applies to you.

○ I am an individual and it is time for my PCR recurrent test.

○ I am an individual and have been flagged on a daily symptom check.

○ I am an individual living alone returning to work after quarantine/isolation.

○ I am an individual with household contacts returning to work after quarantine/isolation.

○ I am a household contact of an individual

☐ I agree to share the above answers for the purpose of signing up for the COVID-19 test.

This site is protected by reCAPTCHA and the Google Privacy Policy and Terms of Service apply.

Submit

Example of Test Results Language

Positive PCR results

Your results indicate that SARS-CoV-2 was detected in the sample you provided. If you have a positive test result, it is very likely that you have COVID-19.

Most people with COVID-19 have mild symptoms. You can pass the infection to others through coughing, sneezing, and talking. It is very important to stay home and limit your interaction with others in your household and in public.

Next Steps

- It's important to share your results with your healthcare provider. Together, you can figure out next steps and create a plan that's right for you.
- If you are an employee or a household contact of an employee, we encourage you to contact the employer through which this test was offered. The employer can help you to figure out next steps to keep you and others around you healthy.
- The decision to return to work should be determined by the employer based on a number of factors, including symptoms and ongoing risk of spreading the virus to others.
- Continue to monitor your symptoms closely, and follow federal, state, and local government guidance regarding social distancing and isolation.
- We recommend that you call your healthcare provider if your symptoms are severe, do not improve, get worse, or you develop new or concerning symptoms. Seek medical attention right away if you experience the following symptoms: trouble breathing, persistent pain or pressure in your chest, new confusion, inability to wake or stay awake, bluish lips or face, or any other symptoms that are severe or concerning to you.
- After receiving your results, you will have an opportunity to speak with a licensed physician from our healthcare provider network partner, PWNHealth, who can answer any questions you may have about your test results and help determine next steps in care at no additional cost.

Our physician partner will try to contact you directly, but you can also schedule your session by calling the PWNHealth Care Coordination Team at 315-401-7865, Monday-Sunday, 8 a.m. to 11 p.m. Eastern Time, or email **covid19@pwnhealth.com**.

Negative PCR results

Your results indicate that SARS-CoV-2 was not detected in the sample you provided. For COVID-19, a negative test result for a sample collected while a person has symptoms usually means that COVID-19 did not cause your recent illness.

However, 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. If this is the case, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of the places you have recently traveled) in deciding how to care for you.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

Next Steps

- The decision to return to work should be determined by the employer based on a number of factors, including symptoms and ongoing risk of spreading the virus to others.
- Continue to monitor for symptoms, and follow federal, state, and local government guidance regarding social distancing.
- If an employee or household contact develops symptoms, contact the employer right away to decide on next steps. Seek immediate medical attention if you experience the following symptoms: trouble breathing, persistent pain or pressure in your chest, new confusion, inability to wake or stay awake, bluish lips or face, or any other symptoms that are severe or concerning to you.
- If you have questions about this test or your results, you can contact the PWNHealth Care Coordination Team at 315-401-7865, Monday-Sunday, 8 a.m. to 11 p.m. Eastern Time, or email covid19@pwnhealth.com . You can also leave a message after hours and a PWNHealth team member will call you back as soon as possible.

Indeterminate PCR results

Your results are indeterminate for SARS-CoV-2. An indeterminate result means that it is neither positive nor negative. You need to be retested in order to confirm whether or not you are infected.

This result can occur if you test too soon from the time you were exposed to the virus. It can also occur if there was a problem with how the sample was collected or the test itself. It is possible that you may have the virus; therefore it is recommended that you take precautions to prevent further spread. If you are infected, you can pass the infection to others through coughing, sneezing, and exhaling. It is very important to stay home and limit your interaction with others in your household and in public while you wait to be retested and receive your results.

Next Steps

- Continue to monitor for symptoms, and follow federal, state, and local government guidance regarding social distancing.
- If an employee or household contact develops symptoms, we encourage you to contact the employer right away to discuss next steps. Seek immediate medical attention if you experience any of the following symptoms: trouble breathing, persistent pain or pressure in your chest, new confusion, inability to wake or stay awake, bluish lips or face, or any other symptoms that are severe or concerning to you.
- If you have questions about this test or your results, you can contact the PWNHealth Care Coordination Team at 315-401-7865, Monday-Sunday, 8 a.m. to 11 p.m. Eastern Time, or email covid19@pwnhealth.com. You can also leave a message after hours and a PWNHealth team member will call you back as soon as possible.