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MANAGEMENT SERVICES

PCR COVID19 DETECTION KIT

PHOENIXDX®
CORONAVIRUS(2019-NCOV)

EXTENDING HELP HOWEVER POSSIBLE

70 S Sandusky Street
Delaware, OH 43015

1.833.548.8378
www.gotraxconnects.com

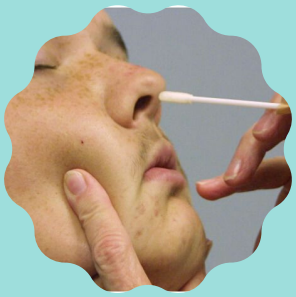
PhoenixDx® 2019-nCov

A Highly Sensitive and Specific, Fast and Efficient COVID19 Test

120
minutes

Duration
It only takes 1.5 to 2 hours to have the results

Requires Swabs



Taken from the nose, throat, or mucus of lung secretions

RT-PCR Machine

PhoenixDx® 2019-nCov

This is a device that uses real-time RT-PCR (see definition below) to detect COVID-19 in suspected patients .

Sometimes called "molecular phototyping", reverse transcription polymerase chain reaction (RT-PCR) is a fast and inexpensive technique used to "amplify"—copy—small segments of DNA.

1. A PATIENT SAMPLE COLLECTION
2. RT-PCR TEST
3. RESULTS

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How does real-time RT-PCR work with the coronavirus?

Extraction of Coronavirus RNA using Swabs

Compared to other available virus isolation methods, real-time RT-PCR is significantly faster and has a lower potential for contamination or errors, as the entire process can be done within a closed tube. It continues to be the most accurate method available for detection of the coronavirus.

Highly Sensitive and Specific

The RNA is reverse transcribed to DNA using a specific enzyme (reverse transcriptase). Additional short fragments of DNA that are complementary to specific parts of the transcribed viral DNA are then added.

These fragments attach themselves to target sections of the viral DNA if the virus is present in a sample. Some of the added genetic fragments are for building DNA strands during amplification, while the others are for building the DNA and adding marker labels to the strands, which are then used to detect the virus.

The mixture is then placed in an RT-PCR machine. The machine cycles through temperatures that heat and cool the mixture to trigger specific chemical reactions that create new, identical copies of the target sections of the viral DNA. The cycle repeats over and over to continue copying the target sections of viral DNA. Each cycle doubles the previous amount: two copies become four, four copies become eight, and so on. A standard real-time RT-PCR setup usually goes through 35 cycles, meaning that by the end of the process, around 35 billion new copies of the sections of viral DNA are created from each strand of the virus present in the sample.

As new copies of the viral DNA sections are built, the marker labels attach to the DNA strands and then release a fluorescent dye, which is measured by the machine's computer and presented in real time on the screen. The computer tracks the amount of fluorescence in the sample after each cycle. When the amount goes over a certain threshold of fluorescence, presence of the virus is confirmed. Scientists also monitor how many cycles it takes to reach this level to estimate the severity of the infection: the fewer the cycles, the more severe the viral infection is.

Why use real-time RT-PCR?

The real-time RT-PCR technique is highly sensitive and specific and can deliver a reliable diagnosis in as fast as two hours, although laboratories usually take between 6 to 8 hours on avergage. Compared to other available virus isolation methods, real-time RT-PCR is significantly faster and has a lower potential for contamination or errors as the entire process can be done within a closed tube. It continues to be the most accurate method available for detection of the coronavirus. To detect past infections, which is important for understanding the development and spread of the virus, real-time RT-PCR cannot be used, as viruses are only present in the body for a specific window of time. Other methods are necessary to detect, track, and study past infections, particularly those that may have developed and spread without symptoms.

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How Coronavirus Testing Works

Real-Time Reverse Transcription Polymerase Chain Reaction (RT-PCR) tests are used to detect genetic material. These tests can be used to screen samples and detect infections at an early stage.

Samples are collected from the nose or throat using a swab and swiftly sent to a lab to be tested.

The samples are mixed with reagents and placed in a machine that duplicates the genetic material.

If the virus exists, the copies made by this machine will confirm its presence. The test is complete.

Samples coming from the nose or throat limit how much of the pathogen can be obtained.

The time it takes the samples to get to the lab is crucial. The pathogen does not remain viable for many hours.

Important Information about PhoenixDx®

Compatible with most Viral RNA Extraction Kits

Compatible with most molecular analyzers

Nuclease free 96 well plates; Hard-Shell Thin-Wall-96 Well Skirted PCR Plates

Micro-seal “B” Adhesive Seals, optically clear

Adjustable pipettes & fitting filtered pipette tips

Suitable storage options for reagents and specimen (4 °C, –20 °C, –70 °C)

Appropriate PPE & workspaces for working with potentially infectious samples

Surface decontaminations such as DNAZap (Life Technologies), DNA Away (Fisher Scientific), RNAse Away (Fisher Scientific), 10% bleach (1:10 dilution of commercial 5.25-6.0% sodium hypochlorite)

Nuclease-free tubes / strips / plates to prepare dilutions and master-mixes, such as Eppendorf colorless 1.5 mL Micro-tubes, Cat. No. Z606340

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Other important Information about PhoenixDx®

INTENDED USE

PhoenixDx® 2019-nCoV is a real-time RT-PCR-based test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasal, nasopharyngeal, and oropharyngeal swabs and bronchoalveolar lavage (BAL) specimens from individuals suspected of COVID-19 infection by their healthcare provider. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

Results are for the identification of SARS-CoV-2 RNA. SARSCoV-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 2019-nCoV 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.

PhoenixDx® 2019-nCoV is intended for use by qualified and trained healthcare professionals or clinical laboratory personnel specifically instructed and trained in the techniques of real-time RT-PCR and in vitro diagnostic procedures. PhoenixDx® 2019-nCoV is only for use under the Food and Drug Administration's Emergency Use Authorization (EUA).

Explanation of the Test/Principles of the Procedure

The PhoenixDx® 2019-nCoV test is based on conventional RT-PCR technology, including extraction and purification of the RNA genome of SARS-CoV-2, followed by reverse transcription to cDNA, PCR amplification, and detection of the target sequences. The test is run on the BIO-RAD CFX96-IVD platform. Nucleic acid from patient samples and controls are extracted in parallel using the RTA Viral Nucleic Acid Isolation Kit. Nucleic acid is released by the lysis reagent and bound to the silica columns. Unbound substances and impurities, such as denatured protein, cellular debris, and potential PCR inhibitors, are removed with subsequent wash steps, and purified nucleic acid is eluted in silica columns with elution buffer. External controls (positive and negative) are processed in the same way with each run.

Other important Information about PhoenixDx® (contd.)

Selective amplification of target nucleic acid from the sample is achieved by the use of target-specific forward and reverse primers and probes specific to the SARS-CoV-2 envelope gene (E-gene) and the polymerase gene (RdRP) https://doi.org/10.2807/1560-7917.ES.2020.25.3.2000045). The dRP gene target is detected by one probe unique to SARS-CoV-2. Additionally, a conserved region in the structural protein envelope E-gene was also chosen for the pan-Sarbecovirus detection. The pan-Sarbecovirus detection sets will also detect SARS-CoV-2 virus. Due to the intrinsic mutation rate of RNA viruses, it is possible that mutations in the target sequence occur and accumulate over time, leading to false-negative results. PhoenixDx® 2019-nCoV mitigates this risk by using 2 different target sequences for SARS-CoV-2.

Selective amplification of the RNase P Internal Control cDNA is achieved by the use of non-competitive, sequence-specific forward and reverse primers and a probe which have no homology with the coronavirus genome. A thermostable DNA polymerase enzyme is used for amplification.

The PhoenixDx® 2019-nCoV master mix contains detection probes for the two SARSCoV-2 targets and one for the internal RNase P gene. Each of the targets is amplified in a separate reaction. Probes are each labeled with fluorescent dyes that act as a reporter. Each probe also has a second dye that acts as a quencher. When not bound to the target sequence, the fluorescent signals of the intact probes are suppressed by the quencher dye. During the PCR amplification step, hybridization of the probes to the specific single-stranded DNA template results in cleavage of the probe by the 5' to 3' exonuclease activity of the DNA polymerase, resulting in separation of the reporter and quencher dyes and the generation of a fluorescent signal. With each PCR cycle, increasing amounts of cleaved probes are generated, and the cumulative signal of the reporter dye increases concomitantly. Each reporter dye is measured at defined wavelengths, which enables simultaneous detection and discrimination of the amplified coronavirus targets.

Materials Provided

Table 1:

PRODUCT	SIZE	SKU
PHOENIXDX® 2019-NCOV	50 rxn / 20 µl	PCCSKU15259

QUANTITY AND VOLUME	COMPONENT
1 x 150 µl	PhoenixDx® **Enzyme Mix**
1 x 750 µl	PhoenixDx® **Sarbeco Mix**
1 x 750 µl	PhoenixDx® **SARS-CoV-2 Mix**
1 x 750 µl	PhoenixDx® **RNase P Mix**
1 x 50 µl	2019-nCoV Target Positive Control **(TPC)**

*Each of the colors above corresponds to the color-coded vials in the test kit.

Other important Information about PhoenixDX® (contd.)

ADDITIONAL REQUIRED MATERIALS NOT PROVIDED

- RTA Viral RNA Extraction Kit as extraction Kit (RTA Laboratories, Cat #09010100) or Qiagen QIAamp MinElute Virus Spin Kit Cat No./ID: 57704 or Roche High Pure Viral RNA Kit (Cat. No. 11858882001)
- BioRad CFX-96 IVD marked instrument with BioRad CFX Manager Software version 3.0 or Qiagen
- Rotor-Gene Q software 2.3.5 or higher, or Applied Biosystems ABI 7500 Fast Real-Time PCR Dx software version 2.0.4 or higher.
- BioRad CFX-96 IVD nuclease free 96 well plates: Hard-Shell Thin-Wall 96-Well Skirted PCR Plates (BIO-RAD, Cat#: HSP-9655)
- BioRad sealing tape: Microseal 'B' Adhesive Seals, optically clear (BIO-RAD, Cat#: MSB-1001)
- Qiagen PCR Tubes, 0.2 mL Cat No./ID: 981008 or Strip Tubes and Caps, 0.1 mL Cat No./ID: 981103
- Thermofisher MicroAmp Fast Optical 96-Well Reaction Plate with Barcode, 0.1 mL, Cat. No. 4366932
- Thermofisher MicroAmp Optical Adhesive Film, Cat. No. 4311971
- Adjustable pipettes & fitting filtered pipette tips
- Appropriate PPE & workspaces for working with potentially infectious samples
- Surface decontaminants such as DNAZap (Life Technologies), DNA Away (Fisher)
- Scientific), RNAse Away (Fisher Scientific), 10% bleach (1:10 dilution of commercial 5.25-6.0% sodium hypochlorite)
- Nuclease-free tubes / strips / plates to prepare dilutions and master-mixes, such as Eppendorf colorless 1.5 mL Microtubes, Cat. No. Z606340
- Nuclease-Free dH2O
- Suitable storage options for reagents and specimen (4 °C, –20 °C, –70 °C)

STORAGE

- Store all components at –20 °C and avoid repeated freeze/thaw cycles.
- Protect the 2X qPCR master mixes from light, as prolonged exposure can diminish the performance of the fluorophores.
- If the kit components have been damaged during transport, contact Procomcure Biotech. Do not use as performance may be compromised.
- Keep reagents separate from the sample material to avoid contamination.
- Do not use after the designated expiry date.

FACT SHEET FOR HEALTHCARE PROVIDERS

PhoenixDx® 2019-CoV– Trax Management Services Inc **April 18,2020** **Coronavirus Disease 2019 (COVID-19)**

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the PhoenixDx® 2019-CoV.

The PhoenixDx® 2019-CoV is authorized for use on using respiratory specimens collected from individuals suspected of COVID-19 by their healthcare provider.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: PhoenixDx® 2019-CoV.

What are the symptoms of COVID-19? Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the CDC webpage for the most up to date information.

What do I need to know about COVID-19 testing?
Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

- The PhoenixDx® 2019-CoV can be used to test in nasal, nasopharyngeal and oropharyngeal swabs and BAL specimens.
- The PhoenixDx® 2019-CoV should be ordered for the detection of COVID-19 in individuals who are suspected of COVID-19 by their healthcare provider.

This test is to be performed only using respiratory specimens collected from individuals suspected of COVID-19 by their healthcare provider.

- The PhoenixDx® 2019-CoV is only authorized for use in laboratories in the United States certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

Specimens should be collected with appropriate infection control precautions. Current guidance for COVID-19 infection control precautions are available at the CDC's website (see links provided in "Where can I go for updates and more information" section).

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of having COVID-19 as outlined in the CDC *Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)*. For additional information, refer to CDC *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19)* (see links provided in "Where can I go for updates and more information" section).

What does it mean if the specimen tests positive for the virus that causes COVID-19?
A positive test result for COVID-19 indicates that RNA from SARS-CoV-2 was detected, and the patient is infected with the virus and presumed to be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions. Patient management should follow current CDC guidelines.

The PhoenixDx® 2019-CoV has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19 patients, limits in the ability to work, the delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

All laboratories using this test must follow the standard testing and reporting guidelines according to their appropriate public health authorities.

What does it mean if the specimen tests negative for the virus that causes COVID-19?
A negative test result for this test means that SARSCoV-2 RNA was not present in the specimen above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions. A negative result does not exclude the possibility of COVID-19.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that COVID19 is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If COVID-19 is still suspected based on exposure history together with other clinical findings, re-testing should be considered by healthcare providers in consultation with public health authorities.

Risks to a patient of a false negative include: delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

What is an EUA?
The United States (U.S.) FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA 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 (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19.

An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in the detection of the virus that causes COVID-19.

The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used).

Where can I go for updates and more information?

CDC webpages:

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

General: https://www.cdc.gov/COVID19 **Healthcare Professionals:**
https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html
Information for Laboratories:
https://www.cdc.gov/coronavirus/2019nCoV/guidance-laboratories.html
Laboratory Biosafety:
https://www.cdc.gov/coronavirus/2019nCoV/lab-biosafety-guidelines.html **Isolation Precautions in Healthcare Settings:**
https://www.cdc.gov/coronavirus/2019-ncov/infection-control/controlrecommendations.html
Specimen Collection:
https://www.cdc.gov/coronavirus/2019nCoV/guidelines-clinical-specimens.html
Infection Control:
https://www.cdc.gov/coronavirus/2019ncov/infection-control/index.html

FDA webpages:

General: www.fda.gov/novelcoronavirus
EUAs:(includes links to patient fact sheet and manufacturer's instructions) https://www.fda.gov/medical-devices/emergencysituations-medical-devices/emergency-use-authorizations

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Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

FACT SHEET FOR PATIENTS

PhoenixDx® 2019-CoV– Trax Management Services Inc **April 18, 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 PhoenixDx® 2019-CoV.

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 PhoenixDx® 2019-CoV?
The test is designed to detect the virus that causes COVID-19 in respiratory specimens, for example nasal or oral swabs.

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?

- **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.

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.

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.