Acūtis

Introducing COVID-19 testing with Acutis Reveal™

In these matters there's no time to waste. Get the answers you need with the accuracy and clarity you've come to expect from us.

Acutis Diagnostics now offers testing for COVID-19 (2019-nCoV) using the SARS CoV-2 Real-time RT-PCR Diagnostic Panel.

Offered under Emergency Use Authorization (EUA), our test validation showed >99% sensitivity and 100% specificity within our test environment.

We are here **for you.**

For more information,
reach out to your Sales Specialist or our Client Care Partners.

↓

844-522-8847

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The SARS-CoV-2 Real-time RT-PCR Diagnostic Panel is authorized for use on respiratory specimens from individuals who meet the Centers for Disease Control and Prevention (CDC) Coronavirus Disease 2019 (COVID-19) clinical and/or epidemiological criteria. CDC COVID-19 criteria for testing on human specimens are available at CDC's webpage, *Information for Healthcare Professionals.*

Acūtis = Accūracy

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

COVID-Ins-2

Device Model: .....

Acūtis Diagnostics

Instructions for **sample collection**

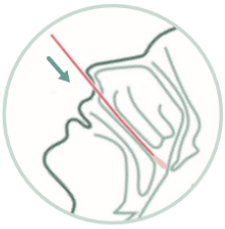
Acutis Reveal™ COVID-19 test

Due to national supply shortages related to COVID-19, nasopharyngeal swabs may be unavailable. Some swabs, typically indicated for other uses, have been tested and approved by the CDC for use in COVID-19 testing.

Clinician should determine method of collection based on swab type and the patient's nasopharyngeal anatomy.

Option 1 - determine if the singular nasopharyngeal swab can be used to collect a sample from the nasopharynx. If yes, proceed as follows:

1



Insert swab into one nostril straight back, NOT upward, and horizontally to the nasopharynx until resistance is met.

2

Rotate the swab up to five times and hold in place for 5 to 10 seconds to collect sample materials.

3

Insert the swab into the viral transport medium.

4

Break handle at the breakpoint line.

Option 2 - if the singular nasopharyngeal swab cannot be used to collect a sample from the nasopharynx, obtain a nasal and an oral sample as follows:

1

While gently rotating the swab, insert swab less than one inch into nostril.

2

Rotate the swab several times against nasal wall and repeat in other nostril using the same swab.

3

Insert the swab into the sterile transport media.

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Acutis reveal™

Pathogen Detected

Status - FINAL COPY

STAT

Patient

Name	Test, Patient
ID	1111-123456
Gender	Male
Birth	9/17/1977

Matrix - Nasopharyngeal Swab

Accession #	222222
Collection Date	4/1/2020 10:00 AM
Received Date	4/2/2020
Reported Date	4/3/2020

Provider

Doctor	Doctor, Doctor
Organization	Sample Organization

Viral (RIT)

Test Name	Outcome
[S] Adenovirus	Not Detected
[S] Coronavirus HKU1 (not novel)	Not Detected
[S] Coronavirus NL63 (not novel)	Not Detected
[S] Coronavirus 229E (not novel)	Not Detected
[S] Coronavirus OC43 (not novel)	Not Detected
[S] Human Bocavirus	Not Detected
[S] Human Metapneumovirus	**Detected**
[S] Influenza A	Not Detected
[S] Influenza A H1/2009H1N1	Not Detected
[S] Influenza A H3	Not Detected
[S] Influenza B	Not Detected
[S] Parainfluenza Virus 1	Not Detected
[S] Parainfluenza Virus 2	Not Detected
[S] Parainfluenza Virus 3	Not Detected
[S] Parainfluenza Virus 4	Not Detected
[S] Respiratory Syncytial Virus A	Not Detected
[S] Respiratory Syncytial Virus B	Not Detected
[S] Rhinovirus/Enterovirus	Not Detected
[S] SARS-CoV-2 (COVID-19)	**Detected**

Notes:

SARS-CoV-2 (COVID-19) testing was performed.

Test system details

This test has been FDA approved under the Emergency Use Authorizations (EUA) for Medical Devices for Coronavirus Disease 2019 (COVID-19). The performance characteristics of the SARS-CoV-2 (COVID-19) assay was validated by Acutis in accordance with the FDA's Guidance Document "Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to Emergency Use Authorization for C oronavirus Disease-2019 during the Public Health Emergency" issued on February 29th, 2020. This test is only authorized for the duration of time t hat circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection of SARS-CoV-2 virus and/or diagn osis of COVID-19 infection under section 564(b)(1) of the Act, 21 U.S.C. 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

The Acutis Reveal RIT tests (excluding SARS-CoV-2) are FDA-cleared RT-PCR assays designed to detect specific nucleic acid targets extracted fr om nasopharyngeal swabs. All results must be considered in conjunction with the clinical history, epidemiological data and other available data. The performance of these assays have not been evaluated in asymptomatic or immunocompromised patients. These assays cannot rule out infections caused by other pathogens not tested. Analyte targets may persist in vivo, independent of virus viability, so detection of analyte target(s) does not i mply that the corresponding virus(es) are infectious or are the causative agents for clinical symptoms. This assay may not be able to differentiate n ewly emerging Influenza A subtypes. False negative results may occur due to the presence of strains with sequence variability or genetic rearrange ments in the target regions of the ARIES Bordetella Assay.

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