PathogenDx
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HEALTHCARE PROVIDER FAQ

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PATHOGENDX DETECTX-RV COVID-19 · CORONAVIRUS DISEASE 2019

This fact sheet Informs you of the significant known and potential risks and benefits of the emergency use of the PathogenDx DetectX-Rv COVID-19 test.

The PathogenDx DetectX-Rv COVID-19 test Is pending FDA EUA authorization for use on respiratory specimens collected from Individuals who are suspected of COVID-19 by their healthcare provider.

All patients whose specimens are tested with this assay will receive the FAQ for patients.

What are the symptoms od COVID-19?
Fever and or symptoms of acute respiratory illness such as cough and difficulty breathing are the main symptoms, however, limited information is available to characterize the full spectrum of illness. Based on what is currently known, signs and symptoms may appear any time from 2 to 14 days after exposure to the SARS-CoV-2 virus. It is believed that the median incubation period is approximately 5 days but may range from 2 to 14.

What do I need to know about COVID-19 testing?
The CDC has the most up to date information regarding COVID-19 testing and is constantly updating this Information at their website. Please see links below.

- The PathogenDx DetectX-Rv COVID-19 test should only be used with Nasopharengeal swabs.
- The PthogenDx DetectX-Rv COVID-19 test should be ordered for the detection of COVID-19 in individuals who are suspected of COVID-19 by their healthcare providers.
- The PathogenDX DetectX-Rv COVID-19 test Is authorized for use in laboratories certified under the CLinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high and moderate complexity tests.

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

Specimens should be collected with appropriate infection control precautions. Current guidance for COVID-19 infection control precautions are available at the CDC's website.

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of having COVID-19 as outlined In the CDC's guidelines. For additional Information please visit the CDC's website.

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

The PathogenDx DetectX-Rv platform has been designed to minimize the likelihood of false test results. However, if a false positive should occur the risks to the patient could Includee the following: a recommendation for isolation, monitoring of household or other close contacts for symptoms, limits in the ability to work, delayed diagnosis and treatment for the true infection causing the symptoms and other unintended affects.

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

What does it mean is the specimen tests negative for the virus that causes COVID-19?

A negative result means that SARS-CoV-2 RNA was not detected in the specimen above the limit of detection. Please know that a negative result does not rule out COVID-19 and should not be used as the only basis for treatment or other patient management decisions.

The possibility of a false negative result should be considered in the context of a patient's exposure history and the presence of clinical symptoms consistent with COVID-19. Although the occurrence is very low, a possibility should especially be considered If additional diagnostic tests Indicate that other causes such as other respiratory illnesses are negative and the patient's exposure history and clinical symptoms indicate that COVID-19 is likely.

Risks of a false negative to a patient include the lack of monitoring infected individuals, delayed or lack of treatment, increased risk to spread infection or other unintended adverse events.

What is an EUA?

The United States FDA has made this test available using their emergency access authority and has named it an Emergency use Authorization (EUA) and 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 (IVD's) for the detection and/or diagnosis of the virus that causes COVID-19.

Where can I go for updates and more information?

CDC webpages:

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/2019-nCoV/guidance-laboratories.html
Laboratory Biosafety:
https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html
Isolation Precautions in Healthcare Settings:
https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html
Specimen Collection:
https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html
Infection Control:
https://www.cdc.gov/coronavirus/2019-ncov/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/emergency-situations-medical-devices/emergency-use-authorizations

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