FACT SHEET FOR INDIVIDUALS
Clinical Enterprise, Inc.  Clinical Enterprise SARS-CoV-2 RT-PCR Assay DTC  April 13, 2021

You are being given this Fact Sheet because you are collecting an individual anterior nasal swab specimen at home using the EmpowerDX COVID-19 Home Collection Kit DTC, and sending your sample for the Coronavirus Disease 2019 (COVID-19) testing using the Clinical Enterprise SARS-CoV-2 RT-PCR Assay DTC.

This Fact Sheet contains information to help you understand the risks and benefits of using this direct to consumer (DTC) product 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 which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can be spread to others not just while one is sick, but even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.

What is the Clinical Enterprise SARS-CoV-2 RT-PCR Assay DTC product?
The product is designed to detect the virus that causes COVID-19 in anterior nasal swab specimens collected at home using the EmpowerDX COVID-19 Home Collection Kit DTC and sent to laboratories designated by Clinical Enterprise, Inc., for COVID-19 testing with the FDA authorized test called the Clinical Enterprise SARS-CoV-2 RT-PCR Assay DTC.

Why should my sample be tested?
You may want to have your sample tested because you or 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
- have been in close contact with an individual suspected of or confirmed to have COVID-19.
- believe there is another reason to investigate your COVID-19 infection status

Testing of your sample 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 you and 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 those you come in contact with.

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.
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