FACT SHEET FOR INDIVIDUALS
Abbott Diagnostics Scarborough, Inc.
BinaxNOW™ COVID-19 Antigen Self Test

You are provided this Fact Sheet because you obtained the BinaxNOW™ COVID-19 Antigen Self Test for testing yourself or dependants for the proteins from the virus that causes COVID-19. The intended use of this test is for testing individuals within 7-days of symptom onset or individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours but no more than 48 hours between tests.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the detection of proteins from the virus that causes 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 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 BinaxNOW™ COVID-19 Antigen Self Test?
The BinaxNOW™ COVID-19 Antigen Self Test is a type of test called an antigen test. Antigen tests are designed to detect proteins from the virus that causes COVID-19 in anterior nasal swabs.

The BinaxNOW™ COVID-19 Antigen Self Test is intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 from individuals within 7-days of symptom onset or individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours but no more than 48 hours between tests.

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 because proteins from the virus that causes COVID-19 were found in your sample. 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). If you test positive with the BinaxNOW™ COVID-19 Antigen Self Test you should self-isolate and seek follow-up care with your healthcare provider as additional testing may be needed.

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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