# FDA Authorizes First Antigen Test to Help in the Rapid Detection of the Virus that Causes COVID-19

*The following is attributed to FDA Commissioner Stephen M. Hahn, M.D. and Jeff Shuren, M.D., director of FDA's Center for Devices and Radiological Health*

The U.S. Food and Drug Administration has issued the first emergency use authorization (EUA) for a COVID-19 antigen test, a new category of tests for use in the ongoing pandemic. These diagnostic tests quickly detect fragments of proteins found on or within the virus by testing samples collected from the nasal cavity using swabs. The EUA was issued late Friday to Quidel Corporation for the Sofia 2 SARS Antigen FIA. This test is authorized for use in high and moderate complexity laboratories certified by Clinical Laboratory Improvement Amendments (CLIA), as well as for point-of-care testing by facilities operating under a CLIA Certificate of Waiver.

Diagnostic testing is one of the pillars of our nation's response to COVID-19 and the FDA continues to take actions to help make these critical products available, including by issuing EUAs. During this pandemic, there have been two types of tests for which the FDA has issued EUAs. One type are polymerase chain reaction (PCR) tests, a molecular diagnostic testing technique that detects the genetic material from the virus and can help diagnose an active COVID-19 infection. The other type are serological tests that look for antibodies to the virus, which can help identify individuals who have developed an adaptive immune response to the virus, as part of either an active infection or a prior infection (serological, or antibody, tests should not be used to diagnose active

infection).

This latest FDA authorization is for an antigen test, which is a new type of diagnostic test designed for rapid detection of the virus that causes COVID-19. Each category of diagnostic test has its own unique role in the fight against this virus. PCR tests can be incredibly accurate, but running the tests and analyzing the results can take time. One of the main advantages of an antigen test is the speed of the test, which can provide results in minutes. However, antigen tests may not detect all active infections, as they do not work the same way as a PCR test. Antigen tests are very specific for the virus, but are not as sensitive as molecular PCR tests. This means that positive results from antigen tests are highly accurate, but there is a higher chance of false negatives, so negative results do not rule out infection. With this in mind, negative results from an antigen test may need to be confirmed with a PCR test prior to making treatment decisions or to prevent the possible spread of the virus due to a false negative.

Antigen tests are also important in the overall response against COVID-19 as they can generally be produced at a lower cost than PCR tests and once multiple manufacturers enter the market, can potentially scale to test millions of Americans per day due to their simpler design, helping our country better identify infection rates closer to real time.

This is just the first antigen test to be authorized and we expect more to follow. We also anticipate providing an EUA template for antigen tests, similar to ones we've released for other test types, to help manufacturers streamline submissions and help expedite our review and issuance of additional EUAs.

Antigen tests will play a critical role in the fight against COVID-19 and we will continue to offer support and expertise to help with the development of accurate tests, and to review and monitor marketed tests to ensure accuracy, while balancing the urgent need for these critical diagnostics.