COVID-19 Update: FDA issues authorization for Quidel QuickVue At-Home COVID-19 test

Today, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the Quidel QuickVue At-Home COVID-19 Test, another antigen test where certain individuals can rapidly collect and test their sample at home, without needing to send a sample to a laboratory for analysis.

The QuickVue At-Home COVID-19 Test is authorized for prescription home use with self-collected anterior nasal (nares) swabs from individuals ages 14 and older or individuals ages 8 and older with swabs collected by an adult. The test is authorized for individuals suspected of COVID-19 by their healthcare provider within the first six days of symptom onset.

“The FDA continues to prioritize the availability of more at-home testing options in response to the pandemic,” said Jeff Shuren, M.D., J.D., director of the FDA’s Center for Devices and Radiological Health. “The QuickVue At-Home COVID-19 Test is another example of the FDA working with test developers to bring important diagnostics to the public.”

In addition to this new prescription home test, Quidel also was issued an EUA in December 2020 for their QuickVue SARS Antigen Test which is authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) to perform high, moderate or waived complexity tests, as well as for point-of-care testing by facilities operating under a CLIA Certificate of Waiver.

The FDA, an agency within the U.S. Department of Health and

Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.