ACON Receives FDA 510(k) Clearance for Flow*flex*® COVID-19 Test; Will be Manufactured in San Diego

SAN DIEGO, CA, November 9, 2023 – ACON Laboratories, Inc. is proud to announce that the U.S. Food & Drug Administration (FDA) has granted 510(k) marketing clearance for the Flow*flex*® COVID-19 Antigen Home Test. This is the first FDA 510(k) for an over-the-counter (OTC) rapid antigen test for SARS-CoV-2, the virus which causes COVID-19. The 510(k) version of the Flow*flex* COVID-19 Antigen Home Test will also be produced domestically, in ACON Laboratories' new 97,000 square foot San Diego manufacturing facility. The 510(k) cleared Flow*flex* COVID-19 Antigen Home Test is indicated for use only by symptomatic individuals within the first *six* days after symptom onset. An initial negative result must be followed by retesting between 48 and 72 hours after the first test. ACON intends to start distribution of the 510(k) cleared test in 2024 and plans additional communications to the market in advance of distribution.

The Flow*flex* COVID-19 Antigen Home Test received Emergency Use Authorization (EUA) in October 2021, as a simple nasal swab test which is easily performed at home without a prescription. It rapidly gained popularity during the Omicron variant surge as ACON manufactured and delivered hundreds of millions of tests to the market. Since then, the intended use of the EUA version of the Flow*flex* COVID-19 Antigen Home Test has evolved based on the collective knowledge of SARS-CoV-2 infections in a population which has been increasingly vaccinated and/or exposed to the virus. Currently, the EUA version is indicated for use by both symptomatic and asymptomatic people. If symptomatic, the test can be performed during the first seven days after symptom onset when tested at least *twice* over *three* days with at least 48 hours between tests. Asymptomatic individuals can use it when testing *three* times over *five* days with at least 48 hours between tests.

The EUA for the Flow*flex* COVID-19 Antigen Home Test has not been revoked, and ACON Laboratories will continue to supply EUA test kits to meet the public's demand for safe and easy home testing through the upcoming cough and cold season.

Michael Lynch, Vice President of Sales & Marketing, commented, "We are pleased to receive the first FDA 510(k) for an OTC COVID antigen test, which is symbolic of ACON's leadership position in the market. This is also the first FDA 510(k) for an OTC rapid antigen test for *any* infectious disease. We believe this represents FDA's commitment to empowering people to take greater charge of their healthcare. The entire ACON team is excited to play a leading role in bringing affordable and reliable home diagnostics for infectious diseases to the public, and hopefully this will be just the first of several such tests to be manufactured at our new state-of-the-art manufacturing facility in San Diego."

Risk Statement: Improper use of COVID-19 Antigen tests can pose significant risk since they may lead to false negative test results. False-negative antigen test results may lead to delayed diagnosis or inappropriate treatment of SARS-CoV-2, which may cause people harm including serious illness and death. False-negative results can also lead to further spread of the SARS-CoV-2 virus, including when people are grouped into cohorts (that is, they are housed together) in health care, long-term care, and other facilities based on these false test results. Actions

to limit exposure based on false-negative results might not be taken, such as isolating people, limiting contact with family and friends, and limiting ability to work.

About ACON Laboratories

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Additional Information for Authorized Distributors and Retail Partners

What does this mean for ACON's authorized distributors and retail partners?
For the immediate future, nothing has changed. The Flowflex EUA has not been revoked. ACON will continue to ship, and you may continue to distribute/sell, the EUA version of Flowflex COVID-19 Antigen Home Test kits which still include asymptomatic testing in the intended use. ACON and its authorized distributors should continue to operate under the conditions of authorization in EUA210494.

What should I do with my EUA Flowflex inventory?
Please continue to distribute/sell your EUA Flowflex inventory. The Flowflex EUA has not been revoked. You do not need to return EUA Flowflex inventory to ACON, and requests to exchange EUA Flowflex for 510(k) Flowflex are not being accepted.

Will the 510(k) version of Flowflex differ from the current EUA version?
The only differences between the current EUA version of the Flowflex COVID-19 Antigen Home Test and the 510(k) version are the intended use and a simplified package insert inside the kit box. The product name, UPC, dimensions, kit contents, 24 month shelf-life, and steps to perform a test are the same.

If the test has not changed, why can't the 510(k) version of Flowflex be used for asymptomatic testing?
FDA 510(k) clearance under K230828 only includes symptomatic testing based on the clinical data which was provided and reviewed. ACON has agreed to submit additional asymptomatic data to support the future addition of an asymptomatic testing claim. Until then, the EUA version may continue to be used for symptomatic and asymptomatic testing, but the 510(k) version may only be used for symptomatic testing.

When will ACON stop shipping EUA Flowflex and transition to the 510(k) version?
EUA Flowflex will remain available through the upcoming cough/cold season and into 2024. A firm transition date has not yet been identified, but ACON will provide further communications to our authorized distributors and retail partners once it has been established.

Can we place a purchase order for 510(k) Flowflex now?
Purchase orders will continue to be filled with EUA Flowflex until the transition to 510(k) Flowflex.

Where will 510(k) Flowflex be manufactured?
A limited quantity of 510(k) Flowflex tests will be manufactured in China as ACON ramps up production at the new San Diego facility. The majority of 510(k) Flowflex delivered to the US market will be manufactured in San Diego, although China will still be available to provide surge capacity if necessary.

Can we place a purchase order specifically for 510(k) Flowflex which was manufactured in San Diego?
Country of origin requests will not be possible for routine orders. If you have or intend to pursue a government contract which excludes tests from China, please contact your ACON account representative to review availability and discuss options.