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Rheonix COVID-19™ MDx Assay Receives Expanded FDA Emergency Use Authorization to Include Saliva as a Sample Type

ITHACA, N.Y. — Rheonix Inc. announced today that the United States Food and Drug Administration (FDA) has issued an expanded Emergency Use Authorization (EUA) for the Rheonix COVID-19™ MDx Assay and now allows the use of saliva as an approved sample type. The fully automated sample-to-answer assay was initially authorized for use on a range of respiratory specimens under EUA on April 29, 2020.

The ability to test saliva samples for the presence of SARS-CoV-2, the virus that causes COVID-19, simplifies the sample collection process and streamlines the testing workflow, while reducing the exposure of medical personnel to potentially infected individuals. For patients, this less invasive sample collection method is a welcome alternative to nasopharyngeal (NP) swabs, the most prevalent sample type. In addition, use of saliva as a sample type helps to ease critical supply chain issues by eliminating the need for specialized swab or collection devices.

“We’d like to thank our colleagues at the Cayuga Medical Center in Ithaca, New York, and Catholic Health System in Buffalo, New York, for their wonderful help in validating the use of saliva,” said Richard Montagna, Ph.D., FACB, senior vice president for scientific and clinical affairs at Rheonix. “Our customers are excited about the addition of this sample type, which will help them conserve precious laboratory resources. We are continuing to expand our COVID-19 tests to help address their ongoing COVID-19 testing challenges.”

The Rheonix COVID-19 MDx Assay is processed on the fully automated Rheonix Encompass MDx® workstation using proprietary Rheonix CARD® cartridge technology. The system requires minimal training to use, and can be quickly installed in critical locations of immediate need. It provides same-day results and is highly scalable, enabling laboratories to move from outsourcing their COVID-19 testing to providing same- or next-day test results for their communities or regions. Rheonix has supported customers’ expanding testing needs by significantly scaling its manufacturing capacity, committing reagent availability to support its customers’ 24/7 testing requirements.

About Emergency Use Authorization Status:
The Rheonix COVID-19 MDx Assay is an endpoint RT-PCR assay intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swabs, oropharyngeal (throat) swabs, anterior nasal swabs, mid-turbinate nasal swabs, nasal washes, nasal aspirates and bronchoalveolar lavage (BAL) fluid from individuals who are suspected of COVID-19 by their healthcare provider. Under the amended EUA, the Rheonix COVID-19 MDx Assay is also for use with saliva specimens collected without preservatives in a sterile tube in a healthcare setting from individuals who are suspected of COVID-19 by their healthcare provider.
The Rheonix COVID-19 MDx Assay has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or

pathogens, and is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

About Rheonix:
Rheonix has developed the suite of Encompass workstations and Rheonix CARD cartridge technology to enable fully automated, sample-to-answer molecular testing for use in clinical, research and applied testing laboratories. With minimal hands-on time, the Encompass systems offer true walkaway simplicity. Rheonix's growing portfolio offers multiplexed testing solutions including the Beer SpoilerAlert™ assay, the most comprehensive beer spoilage panel available; the Listeria PatternAlert™ assay, a rapid method for Listeria strain typing; and the NGS OnePrep™ solution, a fully integrated and automated DNA extraction and library prep solution. Rheonix has received Emergency Use Authorization (EUA) from the FDA for Rheonix COVID-19 MDx Assay, a sample-to-answer test that enables detection of SARS-CoV-2 directly from respiratory samples. The Rheonix STI TriPlex™ Assay and Rheonix Encompass MDx workstation are currently undergoing FDA 510(k) review. For more information, visit www.rheonix.com.

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