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Rheonix Inc. Receives FDA Emergency Use Authorization for Rapid, Fully Automated Molecular COVID-19 Test

- **Sample-to-answer method will enable rapid testing in distributed locations**
- **Rheonix has begun shipments to laboratories under Emergency Use Authorization**

ITHACA, N.Y. — Rheonix Inc. announced today that it has received Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA) for the Rheonix COVID-19™ MDx Assay. The fully automated test enables detection of SARS-CoV-2, the virus that causes COVID-19, directly from respiratory samples. The test is designed to operate on the Rheonix Encompass MDx® workstation, and will facilitate same-day test results for small and medium-throughput laboratories.

The Rheonix COVID-19 MDx Assay is a sample-to-answer test that requires no technician involvement after loading the samples onto the workstation. The system enables cost-effective on-site testing at distributed locations, thus allowing for more rapid decisions regarding isolation and treatment of infected patients. Rheonix has begun shipment of the workstation and test kits to high-need local and regional hospital laboratories to enable them to begin testing immediately.

“Rapid diagnosis is critical in efforts to control the SARS-CoV-2 virus,” said Richard Montagna, Ph.D., FACB, senior vice president for scientific and clinical affairs, Rheonix. “We at Rheonix are grateful to the people on the front lines fighting the spread of the COVID-19 illness, and are proud to be able to support them with a rapid, accurate and automated tool to assist in their efforts.”

The Rheonix COVID-19 MDx Assay is processed on the fully automated Rheonix Encompass MDx workstation using proprietary Rheonix Encompass CARD® cartridge technology. The system requires minimal training to use, and can be quickly installed in critical locations of immediate need. It is ideally suited for use in low to medium-throughput labs, enabling same-day results for local and regional health networks, institutional facilities and rural hospitals.

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 respiratory samples 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, fully automated systems that provide highly multiplexed 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. The Rheonix STI TriPlex™ Assay and Rheonix Encompass MDx® workstation are currently undergoing FDA 510(k) review. Rheonix has received Emergency Use Authorization (EUA) from the FDA for Rheonix COVID-19™ MDx Assay. The rapid sample-to-answer test enables the fully automated detection of SARS-CoV-2, the virus that causes COVID-19, directly from respiratory samples. For more information, visit www.rheonix.com.

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