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Rheonix Inc. to Launch Rapid, Fully Automated Coronavirus Disease 2019 (COVID-19) Assay

Assay to provide small and medium-sized labs access to fast, cost-effective, sample-to-answer testing for public health threat

ITHACA, N.Y. — Rheonix Inc., a leader in highly automated molecular diagnostics, today announced it is developing a coronavirus (COVID-19) test kit for use on its Encompass MDx® workstation. Upon Rheonix's receipt of emergency use authorization (EUA) from the Food and Drug Administration (FDA), the new test will allow for the fully automated detection of SARS-CoV-2 in respiratory specimens, facilitating testing at small and medium-sized labs in distributed locations.

The Rheonix system is a fully automated, sample-to-answer microfluidic system that provides test results in four hours and requires no technician involvement after the sample is loaded. The workstation automatically introduces clinical specimens directly from their barcoded collection tubes into the wells of the microfluidic Rheonix CARD® cartridges, and processes all virus detection reactions on the cartridge within the closed workstation. Once the test is completed, all biological waste remains enclosed in the disposable cartridge and is destroyed. The fully enclosed, self-contained workstation and cartridge system eliminate the technician's need to handle the sample and reduce the possibility for spread of the highly communicable virus.

Due to its relatively low workstation size and cost, low per-sample test cost, and the ability for the assay to be performed by a single technician with no special training, the Rheonix test is easy to implement. It can be rapidly deployed to a broad range of low- and medium-throughput laboratories, including regional hospital labs, physician offices, public health testing sites and clinics.

"A fully automated sample-to-answer testing solution that can be reliably run by small and medium-sized labs will be critical in mobilizing local and regional health networks to fight the COVID-19 public health emergency," said Richard Montagna, Ph.D., FACB, senior vice president for scientific and clinical affairs, Rheonix. "We are grateful that the FDA is providing the flexibility necessary for innovative companies like Rheonix to act quickly to put testing in the hands of those most in need of rapid and dependable methods to control the spread of this virus."

Rheonix is working with a consortium of leading New York state collaborators to test and validate the assay. Inactivated samples of the coronavirus are being provided by ZeptoMetrix, a Buffalo-based company that manufactures biological material for diagnostics development. A leading New York health care network is providing clinical samples and expertise, and Gregory Wilding, Ph.D., chair of the biostatistics department of the University at Buffalo School of Public Health and Health Professions, will validate the results. Rheonix anticipates submitting an emergency use authorization (EUA) to the FDA on the Rheonix COVID-19 MDx assay for the detection of SARS-CoV-2 as soon as validation is complete.

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. For more information, visit www.rheonix.com.

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