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Rheonix Receives FDA Clearance for Fully Automated Encompass MDx® Workstation and Molecular Test for Detection of Sexually Transmitted Infections

Low-cost, scalable, sample-to-answer system provides flexibility and true walk-away testing

ITHACA, N.Y. — Rheonix Inc., an innovative leader in highly multiplexed pathogen detection, today announced that the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance of its automated Encompass MDx® Workstation, along with its STI TriPlex™ Assay and Male Urine Collection Kit for the detection of sexually transmitted infections (STI).

“Rheonix is pleased to announce our FDA 510(k) approval for a diagnostic test kit and for our unique microfluidic workstation that provides true sample-to-answer automation in the clinical laboratory,” said Greg Galvin, Ph.D., founder and CEO of Rheonix. “Throughout the pandemic, the simplicity, flexibility and low cost of the Encompass workstations have enabled laboratories to provide scalable, same-day testing. We are excited to continue building on this platform with a menu of multiplexed panels.”

The fully automated Encompass MDx workstation enables multiplexed sample-to-answer detection, simplifying laboratory workflows and significantly reducing the burden on laboratory technicians. Since early in the coronavirus pandemic, the Rheonix Encompass MDx workstation has been used in combination with the Rheonix COVID-19™ MDx Assay under FDA emergency use authorization (EUA) to enable same-day COVID-19 testing in local and regional laboratories. The easy-to-use, highly scalable system has enabled laboratories to quickly respond to COVID-19 testing surges with existing laboratory staff.

The Rheonix STI TriPlex Assay is approved for simultaneous detection and differentiation of *Chlamydia trachomatis, Neisseria gonorrhoeae* and *Trichomonas vaginalis*, three leading causes of sexually transmitted infection. The assay and collection device are approved for use in male urine samples. Rheonix will seek FDA approval for additional syndromic diagnostic panels that leverage the Encompass MDx workstation’s ability to perform simultaneous detection of multiple target organisms from a single clinical sample. Assays in the Rheonix pipeline include a multiplexed test for simultaneous detection of respiratory pathogens including SARS-CoV-2, influenza and respiratory syncytial virus; a panel of leading organisms that cause gastrointestinal infection; and STI assays with expanded targets and sample types.

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 clinical assays include the Rheonix COVID-19™ MDx Assay for use under FDA emergency use authorization, and the STI TriPlex™ Assay for the detection of sexually transmitted infections in male urine. Applied testing solutions include 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. For more information, visit www.rheonix.com.

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 and saliva 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.

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