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# **ENZO BIOCHEM RECEIVES FDA EMERGENCY USE AUTHORIZATION FOR RAPID EXTRACTION METHOD ON PROPRIETARY TEST SYSTEM FOR DETECTION OF CORONAVIRUS SARS-CoV-2**

NEW YORK, NY, July 20, 2021 (GLOBE NEWSWIRE) -- Enzo Biochem, Inc. (NYSE:ENZ) ("Enzo" or the "Company"), a leading biosciences and diagnostics company, announced today that it has received an expansion of its FDA Emergency Use Authorization (EUA) for the Company's rapid extraction method on its proprietary test system for the detection of coronavirus SARS-CoV-2 including the genetic variants that are now proliferating globally. The EUA enables laboratories to immediately use Enzo's faster extraction process to reduce the time by over one hour, or more than 25%, enabling more test runs on a single instrument. The rapid extraction method can be used on platforms including Enzo's proprietary GENFLEX® automated high-throughput platform, Qiagen's QIA Symphony® SP lower-throughput platform and Enzo's manual workflow. The AMPIPROBE® SARS-Cov-2 Test System includes three components: sample collection, AMPIXTRACT™ SARS-CoV-2 Extraction Kit for sample processing, and AMPIPROBE® SARS-CoV-2 Assay Kit for detection and analysis.

In its letter of authorization dated July 16, 2021, the FDA stated: "Upon review, we concur that the data and information submitted in EUA200260/S003 and S004/A001 supports the requested updates for use with the AMPIPROBE SARS-CoV-2 Test System."

"One of the most important considerations in this EUA is the fact that Enzo's tests successfully detect genetic variants of SARS-Cov-2 including the Delta and Lambda variants that are rapidly spreading throughout the world. This EUA brings the advantages of this platform to testing sites at a time when demand is expected to grow exponentially," said Elazar Rabbani, Ph.D., Enzo CEO. "Our ability to supply advanced technologies to address needs in molecular testing is another reflection of the strength of our fully integrated business model. We are positioned to support rapid scale up and advance the new solutions in molecular testing that can address major challenges like COVID. We have confidence that as we gain approval for additional molecular diagnostic tests currently under development and evaluation that these efficiency measures can be adopted."

Enzo's fully integrated business model allows the Company to rapidly address capacity and

supply limitation issues that have been a significant challenge in the diagnostics market during the COVID-19 pandemic. Enzo manufactures its own sample collection, sample processing, and analytics products and supplies at its GMP-certified facilities. Enzo offers molecular testing as well as immunological testing for COVID-19 that provides direct measurement of neutralizing antibodies.

Enzo previously published a white paper detailing its COVID-19 Antibody Screening Program. Enzo's white papers are available on Enzo's website at:

<https://www.enzo.com/coronavirus>

### **About Enzo Biochem**

Enzo Biochem is a pioneer in molecular diagnostics, leading the convergence of clinical laboratories, life sciences and intellectual property through the development of unique diagnostic platform technologies that provide numerous advantages over previous standards. A global company, Enzo Biochem utilizes cross-functional teams to develop and deploy products, systems and services that meet the ever-changing and rapidly growing needs of health care today and into the future. Underpinning Enzo Biochem's products and technologies is a broad and deep intellectual property portfolio, with patent coverage across a number of key enabling technologies.

For more information, please visit [www.Enzo.com](http://www.Enzo.com) or follow Enzo Biochem on [Twitter](#) and [LinkedIn](#).

### **Forward-Looking Statements**

Except for historical information, the matters discussed in this release may be considered "forward-looking" statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. Such statements include declarations regarding the intent, belief or current expectations of the Company and its management, including those related to cash flow, gross margins, revenues, and expenses which are dependent on a number of factors outside of the control of the Company including, inter alia, the markets for the Company's products and services, costs of goods and services, other expenses, government regulations, litigation, and general business conditions. See Risk Factors in the Company's Form 10-K for the fiscal year ended July 31, 2020. Investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve a number of risks and uncertainties that could materially affect actual results. The Company disclaims any obligations to update any forward-looking statement as a result of developments occurring after the date of this release.

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