

April 19, 2022



## **Enzo Biochem Announces New York State Department of Health Approval of HPV Molecular Diagnostic Test**

**Approval adds HPV to menu of tests available on Enzo's GenFlex® platform, which includes COVID-19 PCR and CT/NG/TV**

NEW YORK, NY, April 19, 2022 (GLOBE NEWSWIRE) -- Enzo Biochem, Inc. (NYSE: ENZ) ("Enzo" or the "Company"), a leading biosciences and diagnostics company, announced that it has received approval from the New York State Department of Health (DOH) for its AMPIPROBE® HPV test. The AMPIPROBE® HPV test is Enzo's PCR-based test designed to detect 14 high-risk human papillomavirus (HPV) variants.

HPV testing is part of Enzo's focus on women's health and oncology and leverages the Company's long history in HPV detection. Almost all cervical cancers are linked to infection with high-risk HPV, an extremely common virus transmitted through sexual contact. With early detection and proper management, cervical cancer can often be treated successfully.

"We are very excited to have received approval for our HPV test from the New York State DOH, representing another important milestone in our continuing efforts to expand the menu of molecular diagnostics tests available on our GENFLEX® platform," said Hamid Erfanian, Chief Executive Officer of Enzo. "We expect to make several other molecular LDT announcements this year and provide a timeline of FDA submissions for US regulatory approval of these tests. The approval process in New York is extremely thorough and requires the exhaustive review of the test's performance. The achievement of this high threshold leaves us well positioned for success as we pursue US and international regulatory approvals."

The U.S. Centers for Disease Control and Prevention estimates that about 79 million Americans are currently infected with HPV, with over 14 million becoming newly infected each year. The American Cancer Society® reported in its annual "Cancer Facts & Figures" that nearly all cervical cancers are caused by persistent HPV infection. Estimates indicate that approximately 14,480 cases of invasive cervical cancer were diagnosed in the United States in 2021, with about 4,290 invasive cervical cancer deaths occurring in the country.

In addition to Enzo's HPV test, the Enzo Clinical Labs team remains committed to improving women's health by offering comprehensive and reliable testing solutions in other areas. Currently, its AMPIPROBE Women's Health Panel is a multiplex nucleic acid amplification test that can detect 16 common targets for sexually transmitted diseases and pathogens, including candida, chlamydia trachomatis, Neisseria gonorrhoeae, trichomonas vaginalis,

ureaplasma, mycoplasma and bacterial vaginosis (BV) on a single APTIMA® swab.

### **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, 2021. 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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### **Enzo Biochem Contacts**

For: Enzo Biochem:

David Bench, CFO  
212-583-0100  
[dbench@enzo.com](mailto:dbench@enzo.com)

For Media:

Lynn Granito  
Berry & Company Public Relations  
212-253-8881  
[lgranito@berrypr.com](mailto:lgranito@berrypr.com)

For Investors:

Bob Yedid  
LifeSci Advisors, LLC  
646-597-6989  
[bob@lifesciadvisors.com](mailto:bob@lifesciadvisors.com)



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