



Applied DNA Launches Mpox Clade I and Clade II Testing Service

STONY BROOK, NY / ACCESSWIRE / September 11, 2024 / [Applied DNA Sciences, Inc.](#) (NASDAQ:APDN) (Applied DNA), a leader in PCR-based DNA technologies, today announced that its wholly-owned clinical laboratory subsidiary, Applied DNA Clinical Labs, LLC (ADCL), has launched an expansion of its clinical testing services for the detection of Mpox (formerly monkeypox) to include testing for both mpox Clade I and Clade II. The launch of the expanded mpox testing service comes after ADCL's interaction with relevant regulatory bodies, including the New York State Department of Health (NYSDOH) and the U.S. Food and Drug Administration (FDA).

"With the launch of the expanded testing services, we believe ADCL is poised to support New York and other states' response to the growing threat of mpox by improving accessibility to testing to equip clinicians with the necessary tools to diagnose and mitigate the virus's spread," stated Dr. James A. Hayward, president and CEO of Applied DNA.

ADCL's Linea™ Mpox Virus 1.0 Assay was previously approved as a laboratory-developed test for the detection of mpox clade II by NYSDOH in September 2022. In August 2024, ADCL conducted additional validation testing showing the Assay can also detect the genetic sequence of mpox Clade I, which is the subject of the World Health Organization's (WHO) 14 August 2024 declaration of a public health emergency of international concern. ADCL will provide the testing service from its CLEP/CLIA molecular diagnostics laboratory in Stony Brook, N.Y.

Laboratory/Test Information

ADCL is a NYSDOH CLEP-permitted, Clinical Laboratory Improvement Amendments ("CLIA")-certified clinical laboratory, certified to perform high-complexity testing. The Linea Mpox Virus 1.0 Assay was developed, and its performance characteristics were determined by ADCL. The Linea Mpox Virus 1.0 Assay has not been cleared or approved by the FDA. The Linea Mpox Virus 1.0 Assay is intended for clinical purposes.

About Applied DNA Sciences

Applied DNA Sciences is a biotechnology company developing technologies to produce and detect deoxyribonucleic acid ("DNA"). Using the polymerase chain reaction ("PCR") to enable both the production and detection of DNA, we operate in three primary business markets: (i) the enzymatic manufacture of synthetic DNA for use in the production of nucleic acid-based therapeutics and the development and sale of a proprietary RNA polymerase ("RNAP") for use in the production of mRNA therapeutics; (ii) the detection of DNA and RNA in molecular diagnostics and genetic testing services; and (iii) the manufacture and detection of DNA for industrial supply chain security services.

Visit adnas.com for more information. Follow us on [X](#) and [LinkedIn](#). Join our [mailing list](#).

Forward-Looking Statements

The statements made by Applied DNA in this press release may be "forward-looking" in nature within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. Forward-looking statements describe Applied DNA's future plans, projections, strategies, and expectations, and are based on assumptions and involve a number of risks and uncertainties, many of which are beyond the control of Applied DNA. In addition, actual results could differ materially from those projected due to the Company's history of net losses and limited financial resources, the unknown demand, revenue and profits, if any, that will result from mpox testing, disruptions in the supply of raw materials and supplies, future changes in the regulatory status of the Linea™ Mpox Virus 1.0 Assay, unknown mpox infection rates in the United States, and various other factors detailed from time to time in Applied DNA's SEC reports and filings, including its Annual Report on Form 10-K,

as amended, filed on December 7, 2023, and Quarterly Reports on Form 10-Q filed on February 8, 2024, May 10, 2024, and August 8, 2024, and other reports it files with the SEC, which are available at www.sec.gov. Applied DNA undertakes no obligation to update publicly any forward-looking statements to reflect new information, events, or circumstances after the date hereof or to reflect the occurrence of unanticipated events, unless otherwise required by law.

Corporate Contacts:

Investor Relations Contact: Sanjay M. Hurry, 917-733-5573, sanjay.hurry@adnas.com

Web: www.adnas.com

X: @APDN

SOURCE: Applied DNA Sciences, Inc.

View the original on accesswire.com

9/11/2024 9:00:00 AM