



Applied DNA Submits Validation Package to New York State Department of Health to Expand Linea Mpx Virus 1.0 Assay to Mpx Clade I

-Validation Studies Confirmed the Assay Can Detect Mpx Clade I and Clade Ib in addition to Clade II-

STONY BROOK, NY / ACCESSWIRE / August 23, 2024 / [Applied DNA Sciences, Inc.](#) (NASDAQ:APDN) (the "Company"), a leader in PCR-based DNA technologies, today announced that its wholly-owned clinical laboratory subsidiary, Applied DNA Clinical Labs, LLC (ADCL), has submitted a validation package to the New York State Department of Health (NYSDOH) in support of an expansion of the permitted use of its Linea™ Mpx Virus 1.0 Assay (the "Assay") to include both mpx clade I and clade II. The Company's validation studies concluded that the Assay's primers and probe have 100% homology to mpx clade I and clade Ib, the latter of which was the subject of the World Health Organization's (WHO) recently declared [public health emergency of international concern](#).

The timeline for NYSDOH's review of the Company's validation package is not currently known and there can be no assurances that NYSDOH will approve the Company's requested expansion of the Assay to clade I.

The Assay was previously approved as a laboratory-developed test for the detection of mpx clade II by NYSDOH in September 2022. If approved for the testing of clade I, the Company could provide clinical testing services in its CLEP/CLIA molecular diagnostics laboratory in Stony Brook, N.Y. for mpx clade I and clade II on samples originating in New York State and in states that recognize New York's CLEP/CLIA certification for testing.

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 Mpx Virus 1.0 Assay was developed, and its performance characteristics were determined by ADCL. The Linea Mpx Virus 1.0 Assay has not been cleared or approved by the U.S. Food and Drug Administration. The Linea Mpx 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.

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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. Further, the uncertainties inherent in research and development, future data and analysis, including whether the Linea Mpx Virus 1.0 Assay will, if ever, receive approval from NYSDOH for the detection of mpx clade I in clinical samples, and/or disruptions in the supply of raw materials and supplies. In

addition, actual results could differ materially from those projected due to the Company's history of net losses, the unknown demand, revenue and profits, if any, that will result from mpox testing, limited financial resources, 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 Report 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.

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