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The Association for Molecular Pathology releases position statement on LDTs

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The Association for Molecular Pathology (AMP) released a special article in the January 2014 issue of the *Journal of Molecular Diagnostics* titled "Revisiting Oversight and Regulation of Molecular-Based Laboratory-Developed Tests"(LDTs). The article was authored by the Laboratory Developed Tests Working Group of the AMP Professional Relations Committee. "The article serves as a re-affirmation of AMP's continued assertion that the CLIA program, in combination with laboratory accreditation programs and professional certification, provides a rigorous and flexible framework for ensuring high quality laboratory testing in the United States," said Elaine Lyon, PhD, AMP President.

The article includes an overview of different group's perspectives on LDTs. Approaches of the FDA and AdvaMed are compared to those of ACLA, CAP, and others including an upcoming HHS report on the issue. Taking all of these viewpoints into account, the AMP report hones in on the specific services integrated within existing LDTs. Unlike traditional medical devices, LDTs rely on the critical role of the laboratory professionals who help design, consult on follow-up testing, and interpret the test results.

This important distinction resulted in AMP's proposal of the term Laboratory Developed Procedures (LDPs) to be used in place of Laboratory Developed Tests, and this is a key element of the paper. The definition of AMP's new term, Laboratory Developed Procedure is: A professional service that encompasses and integrates the design,

development, validation, verification, and quality systems used in laboratory testing and interpretive reporting in the context of clinical care. "The services inherent in LDPs are provided by highly trained laboratory professionals including; pathologists, molecular geneticists, and other clinical laboratory scientists," said Andrea Ferreira-Gonzalez, Chair, AMP LDT Working Group. "The new term accurately describes the integral expertise of the clinical laboratory professional."

The working group also re-affirmed AMP's prior position that some very high-risk tests do require pre-introduction review by a third party reviewer and outlined the types of LDPs to which this would apply. To download a PDF of the article, visit: http://dx.doi.org/10.1016/j.jmoldx.2013.10.003. To view other AMP position statements and letters, visit: http://www.amp.org/publications_resources/position_statements_letters/2013AMPPositionStatements.cfm.

Provided by Association for Molecular Pathology