

FOR IMMEDIATE RELEASE

AMP Issues Statement Regarding FDA Letter to Texas Children’s Hospital and Houston Methodist Hospital about Rapid Detection Zika Test

Bethesda, MD, March 14, 2016:

The Association for Molecular Pathology (AMP), the premier global, professional society serving molecular diagnostics professionals, is very concerned and disappointed to see the [FDA taking enforcement action](#) against the physicians at Texas Children’s Hospital and Houston Methodist Hospital for their [laboratory developed procedure \(LDP\) for Zika virus](#), which was designed to identify virus-specific RNA sequences in a large metropolitan area. Given the ongoing outbreak of the infection and risk of infection in the Houston area, these types of tests are critical for patient care and should be made available to these patients in need.

This case is another clear example of how FDA regulation of LDPs would hinder patient access to vital medical services. FDA’s Emergency Use Authorization for antibody testing at the CDC or state public health labs will not provide results in the timely fashion needed for immediate patient care. In addition, antibody testing has limitations mitigated by molecular testing for Zika.¹ Accurate, timely diagnosis and direct patient care is the primary mission of the molecular pathology professionals at Texas Children’s and Houston Methodist hospitals and other medical centers throughout the country. In an editorial published during the H1N1 outbreak of 2009, past AMP Presidents Dr. Karen Kaul and Dr. Jan Nowak highlighted the role of community molecular diagnostics laboratories in that pandemic and issued a call for better planning in the future.²

AMP has long maintained that the involvement of appropriately trained and qualified laboratory professionals is critical to the development of accurate and reliable laboratory developed procedures, as well as for correct utilization, precise interpretation, and appropriate application of molecular test results. AMP believes the most reasonable and effective path forward is for Congress to insist that the CLIA program modernize, expand its current network of third-party medical experts and utilize scientific expertise from FDA and CDC. CLIA should not relinquish its duties regarding the accuracy and reliability of LDPs. AMP’s proposal builds upon the thousands of successful LDPs, further transforms precision medicine and improves patient care around the country.

For more information on AMP’s past responses to the FDA on its initial proposed regulation of LDT guidance, please visit:

- [AMP Responds to FDA Report on Oversight of Laboratory Developed Testing Procedures](#)
- [AMP Submits Written Testimony for Hearing on “Examining the Regulation of Diagnostic Tests and Laboratory Operations”](#)
- [Congressman Michael Burgess, MD, Speaks at Session on CLIA Modernization of Laboratory Developed Procedures at AMP Annual Meeting](#)
- [AMP Meets with Senate HELP Committee and Presents a CLIA Modernization Proposal](#)
- [AMP Submits Written Comments to FDA on Next Generation Sequencing Regulation, Emphasizing Need for Consistent and Proper Performance of Tests](#)
- [AMP Delivers Oral Comments at FDA Workshop on Optimizing Regulatory Oversight of Next Generation Sequencing Diagnostic Tests](#)
- [AMP Submits Written Comments to FDA on Proposed Regulation of Laboratory Developed Tests](#)

¹ Zika Virus: Diagnostics for an Emerging Pandemic Threat,” by Jesse J. Waggoner and Benjamin A. Pinsky. *J. Clin. Microbiol.* Accepted Manuscript Posted Online 17 February 2016. Online at <http://jcm.asm.org/content/early/2016/02/11/JCM.00279-16.full.pdf+html?sid=015b136e-ed52-44fc-8652-4964152b643b>.

² The Role of Community Molecular Diagnostics Laboratories in the H1N1 Pandemic,” by Jan Nowak and Karen Kaul. *Journal of Molecular Diagnostics*, Vol. 11, No. 5, September 2009. Online at [http://jmd.amjpathol.org/article/S1525-1578\(10\)60253-X/pdf](http://jmd.amjpathol.org/article/S1525-1578(10)60253-X/pdf).

ABOUT AMP:

The Association for Molecular Pathology (AMP) was founded in 1995 to provide structure and leadership to the emerging field of molecular diagnostics. AMP's 2,300+ members include individuals from academic and community medical centers, government, and industry; including pathologist and doctoral scientist laboratory directors; basic and translational scientists; technologists; and trainees. Through the efforts of its Board of Directors, Committees, Working Groups, and members, AMP is the primary resource for expertise, education, and collaboration in one of the fastest growing fields in healthcare. AMP members influence clinical practice, education, and policy on the national and international levels, ultimately serving to advance innovation in the field and protect patient access to high quality, appropriate testing. For more information, visit www.amp.org.

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