



**PRESS RELEASE**  
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## **ACLA Submits Comprehensive Response - Genentech Citizen Petition**

WASHINGTON, D.C. – The American Clinical Laboratory Association (ACLA) submitted a comprehensive response to the December 9<sup>th</sup> citizen petition filed by Genentech with the Food and Drug Administration (FDA). The petition requests a change in FDA policy on the regulation of *in vitro* diagnostic tests developed and performed by clinical laboratories.

Alan Mertz, President of ACLA, in submitting the 24 page response to the FDA Docket said “For the sake of patients and the promise of personalized medicine FDA should deny this petition”. ACLA’s response provides a complete rebuttal to Genentech’s call for FDA to impose a new, unnecessary regulatory framework on all laboratory developed tests (LDTs). Mertz further said “ACLA has provided the FDA with numerous examples of the unique, well-documented benefits of LDTs and their validation. This information should allow FDA to deny the petition thus avoiding the significant, detrimental policy outcome that will result from an FDA decision to accept the petition recommendations”.

ACLA provides several examples of LDT’s that demonstrate the ability of clinical, laboratories to incorporate medical innovations quickly and effectively into patient care services, provide rapid response to disease outbreaks, and provide treatment guidance for patients with rare diseases or in other situations where no FDA cleared test exists. It further notes that LDT’s have a long history of advancing patient care as safe and effective laboratory services and evidence that supports the analytic and clinical validity of these tests. In submitting the response, ACLA offered to work with the government oversight agencies to further refine their policies regarding LDTs. ACLA has proposed a regulatory oversight model to the agencies that allows for continued access to advances in innovative genomic test services while remedying any known concerns, through interagency cooperation with no additional significant new costs.

The comprehensive response can be found on the ACLA web site at <http://www.clinical-labs.org>

ACLA represents local, regional and national clinical laboratories throughout the United States.

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