DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

June 4, 2013

FILE COPY

Alan Mertz
President
American Clinical Laboratory Association
1100 New York Ave, NW, Suite 725 West
Washington, DC 20005

Dear Mr. Mertz:

Your petition to the Food and Drug Administration requesting that FDA (1) refrain from issuing draft or final guidance or a proposed or final rule purporting to regulate LDTs as devices under the FDCA; and (2) confirm in response to this citizen petition that LDTs are not devices under the FDCA, was received by this office on 06/04/2013. It was assigned docket number FDA-2013-P-0667/CP1, and it was filed on 06/04/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Gloria Ortega
Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)