May 21, 2012

The Honorable John Boehner
Office of the Speaker of the House of Representatives
H-232 Capitol Building
Washington, DC 20515-5117

Dear Speaker Boehner:

Recent media reports have indicated that the House of Representatives may include legislation
introduced by Rep. Burgess, H.R.3207, the Modernizing Laboratory Test Standards for Patients
Act of 2011, as part of the “Food and Drug Administration Reform Act of 2012,” when it comes
up for a vote in the Lower Chamber. AACC opposes the inclusion of this bill within the user fee
legislation.

Although AACC is not opposed to additional public or private oversight of Laboratory
Developed Tests (LDTs), as suggested by H.R.3207, we believe it is premature for the House to
take action on this measure given that there are many unanswered questions involving this
legislation, such as:

• What impact would this bill have on patient access to laboratory developed tests? Test
  innovation?
• Would H.R.3207 affect the ability of differing health providers to continue to provide
  LDTs (e.g., hospitals, large and small clinical laboratories, and group practices)?
• What funds would CMS need to implement this new regulatory framework?
• What would clinical laboratories be assessed by CMS to comply with these new
  standards?
• Would new fees adversely impact competition among testing facilities?

AACC requests that you to defer any action on the Burgess bill until these questions can be
answered. We want to ensure that any changes to the regulation of LDTs preserve patient access
to these invaluable tests and not create any new barriers to innovation. AACC looks forward to
working with you to ensure that patients continue to receive safe, timely, and accurate laboratory
testing.
By way of background, AACC is the principal association of professional laboratory scientists--including MDs, PhDs and medical technologists. AACC’s members develop and use chemical concepts, procedures, techniques and instrumentation in health-related investigations and work in hospitals, independent laboratories and the diagnostics industry worldwide. The AACC provides international leadership in advancing the practice and profession of clinical laboratory science and its application to health care. If you have any questions, please call me at (804) 828-0375, or Vince Stine, PhD, Director, Government Affairs, at (202) 835-8721.

Sincerely,

Greg Miller, PhD
President, AACC