August 1, 2012

The Honorable Michael Grimm
US House of Representatives
512 Cannon HOB
Washington, DC 20515

Dear Representative Grimm:

The American Association for Clinical Chemistry (AACC) endorses your legislation, H.R.6118, the "Taking Essential Steps for Testing Act" or "TEST Act," which would modify the Clinical Laboratory Improvement Amendments of 1988 (CLIA'88) to give the Centers for Medicare and Medicaid Services greater latitude in assessing penalties for referring a proficiency testing (PT) specimen to another laboratory. We believe this change is prudent and necessary.

Currently, the CLIA statute requires CMS to apply the same penalty to all laboratories referring a PT sample to another laboratory for analysis, regardless of the intent or severity of the action. The penalty for such an action is severe—the revocation of the CLIA certificate for at least one year. In addition, the owner and laboratory director of that facility are barred from their duties for two years.

Although AACC supports such penalties for laboratories intentionally violating the standards to avoid PT failure, we believe CMS must have flexibility to impose lesser sanctions when a laboratory refers the sample by mistake. For example, a laboratory referring a test because of a 'reflex' policy that requires all positive results for certain test be sent out for confirmatory testing should not be treated the same as a laboratory seeking to 'game' the system. AACC supports your approach for correcting this problem and looks forward to working with you to get H.R.6118 enacted.

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