February 2, 2012

The Honorable Scott Brown
U.S. Senate
359 Dirksen Senate Office Building
Washington, DC 20510

Dear Senator Brown:

The American Association for Clinical Chemistry (AACC) endorses your legislation, S.1493, the "Novel Device Regulatory Relief Act of 2011," which would streamline the Food and Drug Administration's (FDA's) de novo process. We believe that reducing the regulatory burden on manufacturers may lead to greater utilization of this review mechanism, while increasing patient access to innovative test procedures.

Congress authorized the de novo process in the FDA Modernization Act of 1997. This mechanism permits the agency to reclassify low risk devices that would automatically be designated as Class III devices, because there is no predicate device, as Class I or II. This means that manufacturers, in certain instances, are able to seek clearance through the less burdensome 510(k) process, rather than the more costly and onerous pre-market approval (PMA). AACC supports this approach.

Unfortunately, confusion over evidentiary requirements, along with the length of time associated with Agency review, has discouraged many IVD manufacturers from pursuing this route. In each of the past few years, the Office of In Vitro Diagnostics (OIVD) has received only one IVD de novo submission. Since 2005, the length of time for each review has averaged 311 days—50 days longer than the baseline year.

Fortunately, S.1493 would reduce this timeframe by eliminating the requirement that a manufacturer first obtain a Not-Substantially-Equivalent (NSE) finding prior to submitting a de novo petition, as well as permitting the manufacturer to recommend an initial device classification, subject to FDA approval. AACC believes this regulatory change may lead to an increase in the number of de novo applications, while also freeing up additional FDA resources. We support your initiative and look forward to working with you in passing this important legislation.

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