



March 28, 2011

Alberto Gutierrez, PhD  
Director, Office of In Vitro Diagnostic Device  
Evaluation and Safety  
Food and Drug Administration  
White Oak Office Building 66  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Dr. Gutierrez:

The American Association for Clinical Chemistry (AACC) welcomes the Food and Drug Administration's (FDA's) ongoing efforts to ensure that direct-to-consumer (DTC) genetic tests are accurate and their medical claims truthful. Currently, consumers can order such tests and receive the results without input from a health care professional. We are concerned that some individuals, without professional guidance, may make uninformed and potentially harmful health decisions.

AACC supports efforts to empower consumers, so that they can play a more active role in making decisions involving their health care. Some decisions, however, require more knowledge than others. The ordering and interpretation of DTC genetic tests is one of them. AACC believes that qualified health care personnel and genetic testing counselors should play a role in the ordering and interpreting of DTC genetic tests, particularly 'high risk' tests, such as predictive tests for cancer. Misinterpretation of these tests could result in serious, adverse physical and emotional consequences to the consumer.

AACC is also concerned that some DTC entities are making claims that are not supported by medical evidence. A 2010 General Accountability Office (GAO) sting operation of four DTC entities found that many test results were misleading and of "little or no practical use." The GAO further reported examples of "deceptive marketing." AACC encourages the FDA, along with the Federal Trade Commission, to coordinate their efforts to ensure that the claims made by DTC firms are medically substantiated.

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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 (314) 362-0194, or Vince Stine, PhD, Director, Government Affairs, at (202) 835-8721.

Sincerely,

A handwritten signature in cursive script that reads "Ann M. Gronowski".

Ann M. Gronowski, PhD  
President, AACC