**Association for Molecular Pathology**
***Promoting Clinical Practice, Basic Research, and Education in Molecular Pathology***
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**Association for Molecular Pathology Position Statement:**

**Direct Access Genetic Testing** (Direct to Consumer Genetic Testing)

Genetic testing is an integral part of health care and there is great potential for future test development and use. However, genetic tests should be provided to the public only through the services of an appropriate health care professional and a properly certified laboratory. The results of a genetic test must be interpreted in the context of the overall medical evaluation of each individual patient. Genetic tests sold directly to consumers via the Internet, retail stores or pharmacies or over the telephone have the potential to do harm, misleading consumers by making predictions that are medically unproven or not meaningful, promoting the purchase of products not proven to be medically useful and providing, at best, only common sense recommendations.

Direct to consumer genetic testing is an active area of investigation by the United States Government Accountability Office and a recent report raised grave concerns for consumers purchasing these tests (http://www.gao.gov/new.items/d06977t.pdf). We are in agreement with these findings. Genetic testing should be available only through appropriately qualified health professionals that order tests from laboratories that are certified by CLIA for high complexity testing. The Code of Federal Regulations (CFR 493.2) defines those laboratories which must practice under CLIA certification: (http://www.phppo.cdc.gov/clia/regs/subpart_a.aspx#493.1). The genetic tests currently offered directly to consumers are in the categories described:

> "*Laboratory* means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body."

Requesting genetic tests through qualified health professionals from CLIA certified laboratories concurs with the policies of the American College of Medical Genetics (http://www.acmg.net/resources/policies/Direct_Consumer_Testing.pdf) and the College of American Pathologists (http://www.cap.org/apps/docs/statline/pdf/policy_direct_access_laboratory_testing.pdf). In addition to agreement with those stated policies, we support the joint initiatives of the FDA and the FTC to address the issues that arise from direct to consumer testing.

Approved by AMP Council on June 28, 2007