American College of Medical Genetics
Medical Genetics: Translating Genes Into Health™

ACMG Statement on Direct-to-Consumer Genetic Testing

With ongoing genetic discoveries and improvements in technology, more genetic tests are available than ever before. Along with greater availability has come increased consumer demand for genetic tests and expansion of direct-to-consumer (DTC) testing. The American College of Medical Genetics believes that it is critical for the public to realize that genetic testing is only one part of a complex process which has the potential for both positive and negative impact on health and well-being. The College believes that the following should be considered ***minimum requirements*** for any genetic testing protocol:

- **A knowledgeable professional should be involved in the process of ordering and interpreting a genetic test.** Genetic testing is highly technical and complex. A genetics expert such as a certified medical geneticist or genetic counselor can help the consumer determine, for example, whether a genetic test should be performed and how to interpret test results in light of personal and family history. A number of risks can be reduced if a genetics professional is involved in genetic testing. These risks include lack of informed consent, inappropriate testing, misinterpretation of results, testing that is inaccurate or not clinically valid, lack of follow-up care, misinformation, and other adverse consequences.

- **The consumer should be fully informed regarding what the test can and cannot say about his or her health.** Many DTC genetic tests do not give a definitive answer as to whether an individual will develop a given condition, but provide only a risk or probability of developing a disease. The interpretation of such results is often highly nuanced and such information needs to be communicated to the consumer in the appropriate context and in an understandable fashion that is linguistically and culturally appropriate.

- **The scientific evidence on which a test is based should be clearly stated.** DTC genetic test providers should provide easy-to-understand information with primary references documenting the scientific data on which a specific test is based.

- **The clinical testing laboratory must be accredited by CLIA, the State and/or other applicable accrediting agencies.** The accreditation process ensures that laboratories adhere to strict standards and guidelines for clinical testing. Test result reports to consumers should indicate the specifics of the lab's accreditation.

- **Privacy concerns must be addressed.** Prior to testing, the consumer should be informed regarding who will have access to test results, what security is in place to protect these results, what will happen to the DNA sample once testing is complete and how to access a complaint procedure to report breaches of privacy. Also, the issues of possible employment and insurance discrimination and the potential impact on other family members should be discussed prior to obtaining genetic testing.

NOTE: This guideline is designed primarily as an educational resource for clinicians to help them provide quality medical services. Adherence to this guideline is completely voluntary and does not necessarily assure a successful medical outcome. This guideline should not be considered inclusive of all proper procedures and tests or exclusive of other procedures and tests that are reasonably directed to obtaining the same results. In determining the propriety of any specific procedure or test, the clinician should apply his or her own professional judgment to the specific clinical circumstances presented by the individual patient or specimen. Clinicians are encouraged to document the reasons for the use of a particular procedure or test, whether or not it is in conformance with this guideline. Clinicians also are advised to take notice of the date this guideline was adopted, and to consider other medical and scientific information that becomes available after that date.

Approved by the Board of Directors, American College of Medical Genetics April 7, 2008