



## ACMG NEWS

### For Immediate Release

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#### **Expansion of Genomic Tests Prompts Revised ACMG Statement on Direct-to-Consumer Genetic Testing**

**Bethesda, MD – Dec. 17, 2015** | The rapid development of genomic tests offered directly to consumers without the guidance of a knowledgeable medical professional has prompted The American College of Medical Genetics and Genomics (ACMG) to update its statement on minimum requirements that should be in place at any company offering such tests to the public. The new ACMG Statement on Direct-to-Consumer Genetic Testing emphasizes the importance of laboratory accreditation by the Clinical Laboratory Improvement Amendments (CLIA) program or equivalent accrediting body and the necessity of having certified genetics experts available to assist consumers in interpreting test results that have medical implications.

“The new genomic tests being offered to the public are increasingly complex, and the results often must be placed in context with medical and family history to provide meaningful information,” said Gerald Feldman, MD, PhD, FACMG, President of ACMG, the nation’s most experienced organization representing clinical genetic professionals.

The ACMG statement offers education for clinicians and laboratories regarding consumer use of expanded genetic and genomic testing platforms. In addition, it seeks to assist consumers in avoiding the pitfalls of genetic testing that is conducted without the guidance of a certified genetics professional, such as “inadequate or lack of informed consent, testing without the appropriate indications for testing, selecting inadequate methods for testing or selecting the wrong test, misinterpretation of results leading to inappropriate choices for disease management or prevention and inadequate follow-up,” as listed in the updated statement.

“We felt we needed to set the standard high to get in front of a rapidly developing technology that has the potential both for providing useful information but also for introducing misinformation if not handled appropriately,” said Christa Lese Martin, PhD, FACMG, an ACMG Board member currently serving as Vice President for Laboratory Genetics.

To that end, the ACMG recommends that “the consumer should be fully informed regarding what the test can and cannot say about his or her health,” and that “a genetics expert such as a certified medical geneticist or genetic counselor should be available to 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.”

Genomic testing now can provide consumers with information about disease risk factors that must be interpreted within the context of other factors such as environmental exposures and additional health conditions. In addition, testing may return unexpected results that are unrelated to the original reason for testing and may affect not only the individual ordering the test, but also other family members. For these reasons, the ACMG states that “the consumer should be apprised of the potential for receiving results that can neither confirm nor rule out the possibility of disease, or unexpected results that are unrelated to the specific reason for testing, as well as the implications of genetic test results for family members.”

Questions consumers should ask include:

- Is the laboratory performing the test accredited by CLIA?
- Who will have access to the test results?
- Do you have board-certified genetic professionals available to me to help interpret the test results and answer my questions?
- What processes are in place to protect the results?
- What will happen to the DNA once testing is complete?
- Will the data be sold to or shared with any third parties?

The complete **ACMG Statement on Direct-to-Consumer Genetic Testing** is available on our [website](#).

### **About the American College of Medical Genetics and Genomics**

*The American College of Medical Genetics and Genomics ([www.acmg.net](http://www.acmg.net)) is the specialty society representing U.S. clinical and laboratory Medical Geneticists who are board certified by the American Board of Medical Genetics and Genomics, one of the 24 primary member specialty boards of the American Board of Medical Specialties. Fellows of ACMG are from four specialties: MD/DO Clinical Genetics and three MD or PhD laboratory specialties (Clinical Biochemical Genetics, Clinical Cytogenetics, and Clinical Molecular Genetics). ACMG's 1850 members also include genetic counselors, genetics nurses, and public health geneticists. It is the only nationally recognized medical organization dedicated to improving health through the practice of medical genetics and genomics.*

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