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**ACMG Develops New Policy on Risk Categorization for Lab-Developed Tests (LDTs)
for Inherited Conditions**

Bethesda, MD – Jan. 30, 2013 -- The American College of Medical Genetics and Genomics (ACMG) has just released a new Policy Statement on “Risk Categorization for Oversight of Laboratory-Developed Tests (LDTs) for Inherited Conditions.” The Policy Statement was developed by a joint working group of the Laboratory Quality Assurance and the Professional Practice and Guidelines Committees of the American College of Medical Genetics and Genomics. The Statement is available online at http://www.acmg.net/docs/LDT_Release.pdf.

Risk classification has been among the determinants of how medical tests are overseen and regulated by the U.S. Food and Drug Administration (FDA). Therefore, as LDTs for germline (i.e., inherited) mutations continue to proliferate without sound regulatory frameworks in place, an ACMG-appointed workgroup considered the medical risks and implications resulting from germline mutation analysis in a variety of contexts to develop the proposed approach. “This policy statement defines risk associated with clinical molecular testing for inherited conditions from a genetics-centric perspective, based on the opinions of laboratory and clinical geneticists,” said Kristin G. Monaghan, PhD, FACMG and one of the authors of the new statement.

Michael S. Watson, PhD, FACMG, Executive Director of the ACMG said, “We expect and hope that the expert opinion represented in this proposed classification system will be used to guide federal agencies, policymakers and other stakeholders.”

ACMG has categorized testing for inherited conditions by utilizing the three-tiered risk based system, as recommended by the College of American Pathologists (CAP) and consistent with the usual FDA determination of testing-associated risk, whereby FDA aligns risk with the medical decision made on the test results. The ACMG’s proposed risk categorization model is based on how an incorrect result might impact patients and their blood relatives (including offspring). The risk model specifies determining factors for categorization and recommendations for oversight and test interpretation for low, moderate and high levels of risk. It should be recognized that genetic testing is a process including not only the analytical phase addressed in this document, but also preanalytical and postanalytical components, which are beyond the scope of this document. Patient harms can occur in the preanalytical phase (e.g., lack of education/counseling; disregard for the informed consent process; wrong test ordered) as well as postanalytically in the delivery of results and subsequent clinical follow up.

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Due to the potentially serious implications of an incorrect result or interpretation for the patient and the patient's blood relatives, ACMG recommends that all clinical molecular genetic test results be reviewed and interpreted by an individual certified in either Clinical Molecular Genetics (ABMG) or Molecular Genetic Pathology (ABPath/ABMG). The professional interpretation of test results should be provided by an individual certified in Clinical Genetics (ABMG), Clinical Cytogenetics (ABMG), Clinical Molecular Genetics (ABMG), or Molecular Genetic Pathology (ABPath/ABMG). In addition, we recommend that an ABMG certified Clinical Geneticist and/or ABGC/ABMG certified Genetic Counselor provide pre- and post-test counseling to patients, as necessary.

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About the ACMG and ACMG Foundation

Founded in 1991, the American College of Medical Genetics and Genomics (www.acmg.net) advances the practice of medical genetics and genomics by providing education, resources and a voice for more than 1600 biochemical, clinical, cytogenetic, medical and molecular geneticists, genetic counselors and other healthcare professionals committed to the practice of medical genetics. ACMG's activities include the development of laboratory and practice standards and guidelines, advocating for quality genetic services in healthcare and in public health, and promoting the development of methods to diagnose, treat and prevent genetic disease. *Genetics in Medicine*, published monthly, is the official ACMG peer-reviewed journal. ACMG's website (www.acmg.net) offers a variety of resources including Policy Statements, Practice Guidelines, Educational Resources, and a Find a Geneticist tool. The educational and public health programs of the American College of Medical Genetics are dependent upon charitable gifts from corporations, foundations, and individuals. **The ACMG Foundation for Genetic and Genomic Medicine** (www.acmgfoundation.org), a 501(c)(3) nonprofit organization, is a community of supporters and contributors who understand the importance of medical genetics and genomics and genetic counseling in healthcare. Established in 1992, the ACMG Foundation supports the American College of Medical Genetics and Genomics' mission to "translate genes into health" by raising funds to promote the profession of medical genetics and genomics to medical students, to fund the training of future medical geneticists, to support best-practices and tools for practicing physicians and laboratory directors, to promote awareness and understanding of our work in the general public, and much more.