ACMG
American College of Medical Genetics and Genomics
Translating Genes Into Health®

Genetic Tests Are Different than Laboratory Developed Tests (LDTs)

The Issue: As the U.S. Food and Drug Administration (FDA) and Congress evaluate how to regulate LDTs, the American College of Medical Genetics and Genomics (ACMG) urges policymakers to recognize that LDTs used for genetic testing and that inform subsequent treatment or counseling need to be treated differently than other more routine diagnostic tests, to ensure high quality genetic testing remains available to physicians and patients and that it keeps pace with the tremendous innovation we have seen in this field.

Background: Genetic tests are highly complex and do not on their own produce results or point to a treatment plan; they require expert interpretation to ensure their safe and effective use by providers. There are two different approaches to testing for genetic disease: tests that target specific types of variation for conditions such as Down syndrome and acute leukemias, to more open test platforms that sequence the entire genome and provide a comprehensive look at potential contributors to a disease. Entire genome sequencing requires higher levels of geneticist training and expertise, but both kinds of tests require a unique base of specialized medical knowledge and training to ensure both that the proper test is ordered as well as interpreted in the context of individuals and their families. Very few genetic test kits and devices have been approved or cleared by FDA; the great majority of guidance for providers and laboratories has been through the promulgation of standards and guidelines for testing and the development of educational programs by professional organizations such as ACMG. For instance:

- when considering how to approach testing for **spinal muscular atrophy**, it is important to understand the unusual patterns of genetic sequence variation that contribute to diagnosis and prognosis.
- in the testing of **cancer tissues** to inform diagnosis, prognosis, and treatment, it can be important to understand the genetic variation in the tumor and the unaffected tissues of an individual.

ACMG believes that a critical step in the continued improvement of genetic and genomic testing is to better balance the roles of the regulatory bodies involved in the oversight of test kit and device manufacturers and of the practices of clinical laboratories. We urge policymakers to develop a distinct genetic testing regulatory regime which sets high standards for the training, experience and certification of those involved in selecting and interpreting genetic tests; ensures quality management of laboratories; and provides for collection of data that allows continuous quality improvement.

We welcome the opportunity to work with Congress to ensure that genetic and genomic testing is safe and effective for the public, and that we ensure clinical and academic laboratories can quickly innovate and respond to new medical findings and patient needs to deliver on the promise of personalized medicine.

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