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ACLA Supports Physician Guidance in Patient-Centered Genetic Testing

Washington DC – Consumers should seek the guidance of a personal physician or other health care provider in the use of direct to consumer genetic tests to ensure proper understanding of the results and appropriate follow-up, said the American Clinical Laboratory Association (ACLA) today. Recent media reports of genetic tests being marketed and sold directly to consumers in drug stores and other retail establishments have raised concerns.

“Many direct-to-consumer genetic testing companies are not testing individuals for disease – they are testing for the propensity of developing disease conditions,” said Alan Mertz, president of ACLA.

“Although such testing can offer useful information, it requires clear and personal communication between patients and healthcare providers so that steps can be taken to limit the likelihood of developing disease and control its effects.”

Genetic testing is a cornerstone of personalized medicine, bringing better-targeted and more patient-centered care to health delivery. This is translating into longer lives and better quality for patients with leukemia, breast cancer, heart disease, and HIV, among others. Members of the American Clinical Laboratory Association (ACLA) are proud to be at the forefront of delivering these innovative tests in partnership with healthcare providers and the patients they serve.

However, when genetic services are marketed and delivered directly to the consumer—without important input before and after testing from their own physician or personal healthcare provider -- gaps in understanding can lead to damaging consequences. In utilizing and interpreting tests for disease prevention, diagnosis, and monitoring, consumers should rely upon an ordering physician or health care provider with whom they have a personal relationship, and results should not be communicated via long-distance consultations.

ACLA opposes irresponsible direct-to-consumer testing—genetic or otherwise—and supports rigorous state and federal investigation of such testing to determine whether it is in full compliance with regulatory requirements. Clinical laboratories are currently regulated by both federal and state agencies.

There are additional safeguards that the American Clinical Laboratory Association requires of its member laboratories, including the requirement that its members gain accreditation by an independent organization, such as the respected College of American Pathologists (CAP). Such independent accreditation provides important additional assurance that patients are receiving the highest quality test result information and, moreover, that there is a strong patient-physician interaction in connection with testing.

For more information, go to www.clinical-labs.org.

