



**Statement of**

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Pathology (ASCP)**

**before**

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Center for Devices and Radiological Health**

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Oversight of Laboratory Developed Tests  
(LDTs)**

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My name is Kenneth Emancipator, MD, FASCP, and I am an ASCP Officer and Member of the ASCP Executive Committee. I am also a pathologist who spent many years in both industry and clinical setting.

The American Society for Clinical Pathology (ASCP) commends the U.S. Food and Drug Administration (FDA) for engaging stakeholders with extensive interest in Direct to Consumer (DTC) laboratory testing. Your initiative here will help define the impact this type of test has on public health. DTC testing, particularly as it relates to genetic testing, is an area of growing concern to ASCP. ASCP is a patient-centered organization that is committed to optimizing patient health outcomes.

ASCP believes that, in order to ensure optimal patient outcomes, patients choosing DTC tests marketed and sold in direct to consumer commercial transactions should review results with their physicians and utilize CLIA certified laboratories. ASCP believes that the appropriate regulatory framework for DTC testing must simultaneously protect patient health while fostering an environment that encourages the innovation of more advanced testing technology. All testing devices, regardless of their level of complexity or of the qualifications of persons performing the test, should be reviewed before their use on or by patients. Moreover, claims of clinical validity for all devices should be established in an environment similar to that for which they are intended.

Traditionally, physicians have been responsible for ordering diagnostic tests on their patients. DTC genetic testing, however, presents a new paradigm. The rapid developments in genetic testing technology, coupled with the emergence of personal genome testing companies, have created a continuously increasing opportunity for patients to be more involved and to make more decisions about their own health care. This has the potential to be both positive and negative.

DTC testing is becoming an increasingly popular option for patients wishing to monitor their health status. Proponents of DTC testing argue that it provides patients risk assessment information that allows them to proactively search for specific genetic variants of interest. In addition, DTC test access could allow patients to keep certain sensitive test results in private.

While this type of test appears to deliver promise of better health outcomes, ASCP believes that it also presents a myriad of issues not only for patients but also for clinical laboratories, physicians, and insurance companies. These issues include, but are not limited to: (a) medical implications, such as patient understanding of test results; (b) the analytic validity, clinical validity, and clinical utility of the DTC genetic tests in the market today; and (c) the legal implications and liability of DTC testing.

ASCP is concerned that DTC testing will generate undue stress and the “worried well” — individuals who over-interpret their test results. Since DTC test is undertaken outside the context of the physician-patient relationship, appropriate individual and family genetic counseling may be lacking, and consumers become vulnerable to potential harms. To ensure that

patients understand the results of their DTC tests, ASCP recommends that laboratories performing such tests provide patients undergoing testing with easy to comprehend test results. It can also be beneficial for laboratories to make available to the patient, pre-testing information (e.g., the need for fasting, eating or drinking, effect of specific medications, etc.) that may affect test results. If patients are simply given their results and a range of numbers to understand them, there may be both increased false-negatives and false-positives in the test result interpretation, which could possibly lead to increased health care costs as well as adverse impacts on patient health. For optimum patient health outcomes, ASCP also recommends that patients consult with their physician for proper interpretation of the test results. Clinicians may have access to the patient's family history and other data that can critically affect test interpretation and can order additional tests to clarify the results or predict risk.

Even though advances in DNA sequencing technology are broadening its role in the clinical laboratory, we are far from a situation in which we must acknowledge that other forms of "indirect" molecular diagnostics are inferior to DNA sequencing. Currently, the clinical value, if any, of most DTC genetic tests remains unproven. First, the presence of a particular genomic variant in a given individual, though statistically significant, may not necessarily mean that it is clinically meaningful, which is why ASCP believes that it is critical for patients to consult with their physician, use reliable testing sites and pursue appropriate follow-up treatment, if necessary. Second, there are little to no data on the outcomes of these tests. ASCP supports and adheres to the practice of evidence-based medicine and hopes that this concept is applied in the use of personal genomics in health care.

Laws and regulations regarding DTC testing vary by state; therefore, each laboratory performing such tests must operate in accordance with federal and state law. Making sure that an important result is effectively communicated in the DTC setting is more complex than the usual situation of physician ordered tests, where reporting lines are more routine and established. ASCP believes that when patients order their own tests, it is important that the laboratory performing the tests has a strong patient communication and result reporting system.

Lastly, ASCP believes that it is important for physicians and patients to use the DTC test results as a mechanism to discuss a variety of health-related issues and future laboratory testing needs if necessary. It is essential that patients who choose to engage in DTC testing select a CLIA certified laboratory and have their test results reviewed by their primary care physician. ASCP thanks the FDA for the opportunity to present our views and concerns regarding DTC genetic testing. We look forward to the next steps the FDA will undertake in exploring this issue.

ASCP is a professional society with 130,000 members working as pathologists, residents and other physicians, pathologists' assistants, laboratory professionals, medical students and laboratory students. ASCP is committed to developing and maintaining public policies that improve public health and the quality of pathology and laboratory medicine.