

Laboratory Developed Test Oversight

Principle II: Personalized medicine (PM) laws, regulations, and policies must preserve physician discretion to utilize and/or direct the use of the most appropriate diagnostic and treatment options and ensure that physicians are part of the PM team.

Issue: Regulation of laboratory developed tests (LDTs), including genetic tests. Assuring the quality of genetic tests is important in delivering optimal care to patients. Accordingly, we support regulation of LDTs including tests for genetic and acquired mutations that will ensure accuracy, reliability, and validity. Regulations should recognize the importance of the physician's role in the practice of medicine, and should not unduly restrict access to tests that physicians deem necessary and appropriate in the care of their patients.

Definitions:

Definition of genetic test: an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects inherited genotypes, mutations, or chromosomal changes.

Definition of LDT: an in vitro diagnostic test that is developed, validated and used for in-house pathology and diagnostic purposes, and intended for use only by the laboratory entity in which it is developed. This definition of LDTs is intended to be inclusive of tests that detect both inherited and acquired mutations. Outside of the context of this document, tests that detect acquired mutations may sometimes be referred to as "genetic tests."

Proposed regulatory framework for LDTs:

- Tiered, risk-based approach that confers assurance of analytic and clinical validity for all LDTs including genetic tests
- Risk determined by potential of a misinterpreted result to cause harm to patient, and by test characteristics, e.g., test methodology that is not transparent nor well understood (as in the case of tests that use complex algorithms to produce results) would be in highest risk category
- Regulatory approach includes collaboration and engagement of groups that have experience in accreditation and proficiency testing for laboratories conducting genetic tests, such as the College of American Pathologists and the American College of Medical Geneticists
- Preserves physician's right to choose test that he/she determines is appropriate for the clinical situation, whether or not it is a LDT or is FDA-approved/cleared
- Labeling of drugs for which tests inform indication and dosage decisions should not include the brand name of the test, nor make stipulations that the drug can only be prescribed with the prior use of an FDA-approved/cleared test