



Association for Molecular Pathology

Promoting Clinical Practice, Basic Research, and Education in Molecular Pathology

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AMP Releases Statement on Oversight of Laboratory Tests

The Association for Molecular Pathology releases a position statement on the oversight of laboratory developed tests to foster discussion among stakeholders and meets with the Food & Drug Administration.

Bethesda, MD—January 28, 2010— Today, the Association for Molecular Pathology (AMP) released its [new position statement](#) on the oversight of laboratory developed tests (LDTs), a recent focus of debate among policy makers, the laboratory community and other stakeholders. AMP’s statement outlines the organization’s commitment to providing high quality tests and its recognition of the need for implementation of appropriate oversight mechanisms. The association also met with officials from the United States Food and Drug Administration tasked with reviewing applications for diagnostic devices to inform them of the new position statement and discuss FDA’s approach to regulating tests.

In recent years, there has been increased attention on the oversight of LDTs among policy makers, manufacturers, regulators and the laboratory community. While AMP believes that current mechanisms are sufficient in ensuring patient safety and broad access to high quality tests, AMP is taking this opportunity to elucidate its position on the issue.

“We believe that laboratory developed tests are an essential and central component of clinical care,” said AMP President Dr. Karen Mann. She continued, “There is no evidence that the current oversight system has been inadequate or that there have been systemic problems.”

In its position statement, AMP highlights that laboratories performing molecular tests are subject to the Clinical Laboratory Improvement Amendments and all laboratory directors are extensively trained professionals who adhere to all training requirements, certifications, licensure, and other regulations. Dr. Mann stressed the need to foster innovation, “As policymakers, regulators, and other stakeholders consider modifying the current oversight process, AMP urges them to ensure continued patient access to testing.” AMP calls for stakeholders to avoid proposals that would hinder innovation in diagnostics, slow the rapid development and modification of necessary tests and impede the practice of medicine as all specialties rely on diagnostic tests.

AMP’s specific recommendations include:

- Laboratory directors or medical directors should review and reaffirm their policies and procedures for reviewing and documenting that appropriate validation studies have been performed for all tests developed in their laboratories with due consideration of clinical utility and clinical utilization.

- CLIA should reassess utilization of resources and enforcement capabilities in order to meet its current mandate. CLIA should strengthen its enforcement capabilities by hiring more inspectors and improve the training of its inspectors.
- To increase transparency, CMS should make information collected from laboratories in the CLIA program available and easily accessible to the public and other regulators.
- Proficiency testing is a requirement of certification. When a formal proficiency testing program is not available, laboratories must perform and document alternative assessments as directed by CLIA.
- Some tests may require greater scrutiny, such as those with hidden or nontransparent algorithms, and should be subject to additional review by regulators.
- All LDTs should be subject to the same oversight mechanisms, and molecular tests should not be unduly scrutinized.
- Any changes to the current oversight system should occur after a formal rule making process or statutory change.

About AMP

The Association for Molecular Pathology is an international medical professional association dedicated to the advancement, practice, and science of clinical molecular laboratory medicine and translational research based on the applications of molecular biology, genetics and genomics. Through the efforts of an enthusiastic membership from across the United States and around the world, AMP continues to grow in numbers and influence. The organization is divided into the scientific subdivisions of genetics, infectious diseases, hematopathology, and solid tumors. Each subdivision addresses issues, identifies goals, shapes policy, and provides member benefits specific to that particular discipline. The AMP membership includes individuals from academic medical centers, independent laboratories, government, and industry, including physicians, laboratory directors, scientists, medical technologists, and trainees. AMP members populate the majority of clinical molecular diagnostic laboratories in the United States. AMP members are at the forefront of the development and implementation of novel molecular diagnostic tests, whether these are laboratory developed or commercially developed. AMP promotes molecular testing that is consistent with the highest standards established by CLIA, the College of American Pathologists (CAP), the American College of Medical Genetics (ACMG), and FDA. AMP members proudly accept their responsibilities in assessing the analytical validity, clinical validity, clinical utility, and the clinical utilization of molecular tests for each specific patient.

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