



**Association for Molecular Pathology**  
*Promoting Clinical Practice, Basic Research, and Education in Molecular Pathology*

9650 Rockville Pike, Bethesda, Maryland 20814

Tel: 301-634-7939 • Fax: 301-634-7990 • Email: [amp@amp.org](mailto:amp@amp.org) • [www.amp.org](http://www.amp.org)

February 12, 2007

RE: AMP Comments to CLIAC, February 14, 2007

Greeting:

I am Angela Caliendo, Past-President of The Association for Molecular Pathology (AMP) and Associate Professor of Medicine/Associate Professor of Pathology & Laboratory Medicine/Vice Chair, Clinical Pathology/Director, Emory Medical Laboratories/Medical Director, Microbiology Laboratory and Medical Director, Molecular Diagnostics Laboratory at the Emory University School of Medicine. I am here today to represent AMP's comments on the recent tabling of the proposal to introduce a genetics specialty into the CLIA regulations.

The Association for Molecular Pathology (AMP) is an international medical professional association representing over 1,400 physicians, doctoral scientists, and medical technologists who perform genetic testing, as well as other testing, based on knowledge derived from molecular biology, genetics, and genomics. AMP members practice their specialty in academic medical centers, community hospitals, independent clinical laboratories, and federal and state health facilities. For the last several years AMP has provided national leadership to advance safe and effective practice and education for molecular diagnostic testing in the health care industry.

AMP agrees that oversight of genetic testing is an important topic for discussion. Recent advances in genetics and genomics has led, and most likely will continue to lead, to the development of new laboratory tests and services. We expect that advances in human genetics will further facilitate diagnosis and management of disease, guide development and use of pharmacological agents, and offer the ability to predict disease susceptibility before the onset of symptoms when interventions might be most effective. In addition, genetic testing will allow patient and target-specific disease therapies.

In our view, the CLIA regulations and the professional guidelines from the College of American Pathologists (CAP) and the American College of Medical Genetics (ACMG) provide a productive framework for continuous improvement in the quality of genetic testing. Participation in proficiency testing programs such as those administered jointly by the CAP and ACMG provides critical feedback that fosters improved laboratory performance. AMP supports the continuation and expansion of these programs, with the goal of building upon their strengths.

At the technical level, the diagnosis of genetic disease by molecular methods does not differ significantly from the same techniques used to diagnose infectious and neoplastic diseases. Therefore, it is logical that we do not support new stringent technical and personnel standards for molecular genetic testing that would not also apply to molecular oncology and molecular microbiology testing. Where molecular genetic testing *is* unique is in the pre- and post-analytic phases, with particular attention to appropriateness of test ordering and accurate translation of the full clinical implications of test results. Additional standards for laboratory directors, if developed, should acknowledge a range of interpretive complexity for genetic tests from relatively straightforward to highly sophisticated and provide for qualification based on factors to include training, experience, and continuing education. We also recognize that the issue is complex and that well intentioned but poorly deliberated changes to the regulation could produce unanticipated negative effects at a later time.

AMP, which represents the broadest constituencies involved in molecular diagnostic testing, offers the expertise of its membership to partner with regulatory agencies to identify possible regulatory and non- regulatory approaches that will address concerns without stifling innovation or negatively impacting patient care.

Comments approved by AMP Council,

A handwritten signature in black ink, appearing to read 'Andrea Ferreira-Gonzalez', with a long horizontal line extending from the bottom of the signature.

Andrea Ferreira-Gonzalez, PhD  
President