



## Association for Molecular Pathology

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

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21 September 2009

Willie E. May, Ph.D., Director  
Michael D. Amos, Ph.D., Biosciences Advisor to the Director  
Chemical Science and Technology Laboratory  
National Institute of Standards and Technology  
U.S. Department of Commerce  
Gaithersburg, MD, 20899

Dear Dr. May and Dr. Amos,

On behalf of the Association of Molecular Pathology (AMP), I thank you for your leadership on the development of standards and reference materials for molecular medicine. AMP is an international medical professional association representing approximately 1,700 physicians, doctoral scientists, and medical technologists who perform laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. AMP has been grateful for the opportunity to collaborate with you in the past and hopes that there will be additional pathways to partner in the future.

We recently reviewed your draft roadmap document titled, "Measurement Science and Measurement Standards to Support Innovation in Healthcare." AMP commends you for exploring roles for NIST in healthcare and biomedical science and applauds your effort to identify needs to aid and propel innovation.

We are writing to you today to provide you with constructive feedback on the document and to offer additional comments that we think will be helpful as you revise this paper. We recognize that this is an early draft and the first to be circulated for public comment, and we appreciate the opportunity to convey our significant concerns about the document as a whole. The current document fails to acknowledge already successful or in progress efforts to develop standards and calibrators and, as such, it is in some ways a step back rather than a roadmap forward. Additionally, we have concerns that the document lacks prioritization of the greatest needs in standards development, which is needed to truly advance the field of molecular pathology. The following pages include our recommendations and comments to strengthen and improve this document.

AMP members are also available to meet with you in person or by telephone to further discuss our recommendations and comments. For your review, we have enclosed comments we provided to the House Science & Technology Committee regarding the immediate and long-term needs for standards development in biotechnology at NIST.

Thank you very much for your attention and we look forward to future correspondence and collaborations. Please feel free to contact Mary Williams at AMP: [mwilliams@amp.org](mailto:mwilliams@amp.org).

Best regards,

Jan Nowak, MD, PhD  
AMP President

To strengthen the document, please include references and sources for all statistics and claims. Supporting factual information will encourage Congress, policy makers and other stakeholders to implement projects to address the gaps and needs you identify in the document and not dismiss your suggestions based on what they view to be assumptions.

Reference and include descriptions of past efforts to develop standards for genomic medicine including the Clinical & Laboratory Genetics & Genomics Standards (CLGGS) initiative, the External RNA Controls Consortium (ERCC), the MicroArray Quality Control (MAQC), the CDC GeT-RM project, and efforts within NIST itself.

Conduct wider outreach to and solicit comments from stakeholders in molecular diagnostics, including AMP, the American Society for Microbiology, the American Society of Human Genetics, the American College of Medical Genetics, the College of American Pathologists, the American Society for Clinical Pathology, the American Clinical Laboratory Association (ACLA), as well as patient groups.

On page 5, change “economic security” to “economic stability” to better align with other policy discussions.

Page 6, in “Section I,” please include a statement about the dearth of proficiency testing for the majority of marketed diagnostics and the role of CLIA and FDA in ensuring high quality tests.

Page 7, please include AMP as an organization that has articulated the need for additional measurement infrastructure.

Page 9, paragraph “e”, the meaning of this paragraph is unclear. Please define “standard assay formats” and “standards authority.” Are you referring to FDA clearance as the “gold standard”? If so, please also recognize the significance of CLIA and other certification and accreditation programs.

Page 10, some stakeholders are missing including AMP, tools manufacturers and agencies, like the FDA. AMP encourages you to reach out to these stakeholders and seek additional input for this document.

Page 25, AMP agrees with the 2<sup>nd</sup> paragraph and encourages NIST to explore a role it can play in the development of bioinformatics infrastructure to store large quantities of genomics data with the functionality to enable complex analyses.

Page 27, “Standards for RNA Sampling and Storage.” Acknowledge the efforts of the External RNA Controls Consortium to develop standards for RNA sampling and storage.

Page 42, Appendix C. Acknowledge the work of the HHS Office of the National Coordinate for Health IT and its advisory committee subgroups on genetic testing and family history. Some of the work described in this appendix might have already been completed by the national efforts to harmonize and implement Health IT.