



**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@asip.org](mailto:amp@asip.org) • [www.amp.org](http://www.amp.org)

28 March 2007

AMP's Response to Proficiency Testing and Workgroup Meeting (PTWG)

AMP is an international not-for-profit educational society representing over 1,400 physicians, doctoral scientists, and medical technologists who perform molecular diagnostic testing based on nucleic acid technology. AMP members practice their specialty in widely diverse settings: academic medical centers, independent medical laboratories, community hospitals, federal and state health laboratories, and the *in vitro* diagnostic industry. In this capacity, AMP members are involved in every aspect of molecular diagnostic testing: administration and interpretation of molecular diagnostic tests, research and development, and education. For the last several years AMP has provided national leadership for the advancement of safe and effective practice and education for molecular diagnostic testing in the health care industry.

Overall AMP applauds the mission and goal of the PTWG and its members. Molecular testing is a rapidly growing field in which PT materials seriously lag behind. As new genes are discovered and corresponding clinical testing is developed, PT can sometimes take years to become widely available. For smaller laboratories, the cost of the most common PT program (CAP) may become cost prohibitive when the assays are batched in such a way that a lab must order PT for multiple assays but may only be performing one of the included assays. We also have the issue of rare disorders where one or a few laboratories in the world may test a rare condition. Some of the rare disorder testing may rely on gene sequencing where a generic PT program could be implemented for a platform as opposed to an analyte. PT materials do not exist for newer technologies that detect copy number variants or epigenetic changes for esoteric infectious disease organisms or antimicrobial resistance genes. We are willing to work with the PTWG to develop a gap analysis to determine where PT materials are needed in molecular pathology. We also acknowledge the ideas put forth by the working group to incorporate more challenges in the area of test interpretation and limitations. This is critical to increasing the educational value of PT.

Thank you for the opportunity to comment on this very important document. AMP, whose members are routine users of PT, is ready to work with PTWG to promote the development of PT for molecular pathology. In addition, AMP would welcome an invitation to participate as a member of the PTWG in the future. Please do not hesitate to contact V.M. Pratt, PhD, AMP Clinical Practice Committee Chair at [victoria.m.pratt@questdiagnostics.com](mailto:victoria.m.pratt@questdiagnostics.com) if we can be of further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read 'Andrea Ferreira-Gonzalez', written over a horizontal line.

Andrea Ferreira-Gonzalez, PhD  
President