



**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)

December 2, 2008

Dr. David Wood  
World Health Organization (WHO)

**RE: AMP's Support of NIBSC for Development of Certified Reference Materials for the World Health Organization**

Dear Dr. Wood:

The Association for Molecular Pathology (AMP) is an international medical professional association representing approximately 1,600 physicians, doctoral scientists, and medical technologists who perform laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Since the beginning of our organization we have dedicated ourselves to the development and implementation of molecular diagnostic testing, which includes genetic testing in all its definitions, in a manner consistent with the highest standards established by the Clinical Laboratory Improvement Act (CLIA), the College of American Pathologists (CAP), the American College of Medical Genetics (ACMG), and the United States Food and Drug Administration (FDA). Our members lead and work at the majority of clinical molecular diagnostic laboratories in the United States as well as in laboratories in many other countries. We are frequently involved in the development of novel molecular tests, and in the validation of laboratory developed or commercial assays.

AMP strongly endorses the Fragile X syndrome reference materials presented by UK NIBSC (UK National Institute for Biological Standards and Control) to the WHO (World Health Organization). AMP believes that a formal adoption of these reference materials by the WHO would promote quality assurance in the development and calibration of new testing platforms, foster good laboratory practices, and facilitate in the assessment of assay variability among testing centers. This would serve to benefit the accuracy of diagnosis for Fragile X syndrome world wide.

AMP also recognizes the urgent need for traceable certified reference materials for other molecular diagnostic tests related to inherited disorders, oncology (somatic and inherited), pharmacogenomics and infectious diseases. Therefore, the adoption by the WHO, of universally accepted genomic reference materials for Fragile X testing as well as other materials still in development (Prader-Willi/Angelman syndromes, BCR-ABL translocation, and Hereditary Nonpolyposis Colorectal Cancer), will represent a major landmark in the field of personalized medicine, promoting safe, accurate and reliable molecular diagnoses.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jan A. Nowak'. The signature is fluid and cursive, with a prominent 'J' and 'N'.

Jan A. Nowak, MD, PhD  
President