



Association for Molecular Pathology

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

9650 Rockville Pike, Bethesda, Maryland 20814

AMP Comments at FDA Meeting on Array-Based Tests

Bethesda, MD (June 30, 2010): Today, the Association for Molecular Pathology (AMP) presented comments at the US Food & Drug Administration's public meeting on array-based cytogenetic tests. The FDA convened the meeting to seek answers to more than a dozen questions they had on how to evaluate the performance, interpret results and report findings of array-based cytogenetic tests for copy number variation (CNV).

AMP believes array-based cytogenetic tests provide much higher resolution than traditional karyotyping, with expansive capabilities to diagnose and identify causes of genetic syndromes due to chromosome abnormalities. The standard of care in molecular and cytogenetic laboratories as well as genetics clinics is shifting from traditional karyotyping to array-based cytogenomic analysis. "This new technology has provided diagnoses that would have otherwise not been possible with older methods," explained Dr. Mark Sobel, AMP Executive Director.

Professional societies, such as AMP, are currently working to develop professional practice guidelines to address many of the questions raised by the FDA that focus on interpreting and reporting results of array-based cytogenetic tests. AMP believes that the interpretation of these tests falls within the scope of professional practice and that while the FDA should evaluate the technology platform for analytical validity, the FDA does not need to review each possible CNV result. "It is important to remember that all testing is performed in the context of the phenotype of the patient, and interpretation of laboratory data is a collaboration between the clinical scientist and the treating physician," said Dr. Sobel. AMP encourages the FDA to partner with professional associations to collaborate on the best manner to standardize the use and reporting of array-based tests.

AMP believes that to advance the use of array-based cytogenetic tests, the molecular cytogenetic field needs to collect data on both the laboratory results and clinical information. Dr. Sobel added, "Such a database will enable the community to continually assess the validity of results and accelerate the understanding of the results." AMP encourages the government to fund clinical research to further explore the associations between array findings and health information.

About AMP:

The Association for Molecular Pathology (AMP) 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. For more information, please visit: www.amp.org.

CONTACT:

Mary Steele Williams
mwilliams@amp.org
(301) 634-7921