



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

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**Comments to the Agency for Healthcare Research and Quality on the draft
Technology Assessment: “Update on Horizon Scans of Genetic Tests Currently
Available for Clinical Use in Cancers”**

January 14, 2011

Thank you for the opportunity to submit comments on the Technology Assessment (TA), “Update on Horizon Scans of Genetic Tests Currently Available for Clinical Use in Cancers.”

The Association for Molecular Pathology (AMP) is an international medical and professional association representing approximately 1,800 physicians, doctoral scientists, and medical technologists who perform laboratory testing based on knowledge derived from molecular biology, genetics and genomics. Membership includes professionals who work within academic medicine, government, and the *in vitro* diagnostics industry. First, the term “genetic test” and its definition are used both too liberally as well as sometimes incorrectly in the document. The document includes and summarizes numerous tests that are not typically considered genetic or even molecularly based, *i.e.*, not dependent upon the analysis of DNA or RNA. **If AHRQ wishes these tests to remain in the document and for the document to remain factually correct, AMP strongly encourages the authors to rename the TA a scan of laboratory tests, or at least genomic tests, and not strictly genetic tests.** As for genetic testing, this list is incomplete. An example is testing for mutations in the *PMS2* gene associated with non-polyposis colorectal cancer (Lynch syndrome), which was first offered in 2008. Additionally, the definition of genetic test included on page 9 of the TA is erroneously cited as being from the Secretary’s Advisory Committee on Genetics, Health and Society 2008 report on *US System of Oversight of Genetic Testing*. However, the definition in the TA is actually the definition from the Secretary’s Advisory Committee on Genetic Testing report on *Enhancing the Oversight of Genetic Tests* issued in 2000. **AMP requests that the authors modify the TA to use the more recent definition of genetic tests.**

It is important for the value of the document that a distinction be made between genomic tests that assess inherited genetic mutations, acquired somatic mutations, and pharmacogenomics (tests for common genetic variation involved with therapeutic drug response)). Additionally, AMP recommends that predictive genetic testing be distinguished from diagnostic testing. All of these distinctions will help to ensure that the report is viewed as a credible and useful tool by private and public payers and other policy makers.

AMP has previously submitted comments and sent letters to federal agencies on the nomenclature used to describe molecular tests. **Whenever possible, AMP encourages the authors to describe tests based on their molecular entities rather than their**

brand names since numerous labs might offer the same or similar test under a different name. By listing tests using their brand names, some may read this as a *de facto* endorsement of one test over another by the agency, something AMP suspects AHRQ does not intend.

The authors may be aware that stakeholders and federal regulators are currently engaged in discussions on the appropriate oversight of laboratory-developed tests (LDTs). In contrast to *in vitro* diagnostic test kits, most LDTs are developed and validated for use in a single laboratory and currently not subject to FDA approval or clearance. Developers of LDTs do not consider themselves to be manufacturers as they do not manufacture or produce products, *i.e.*, test kits, for sale. **AMP requests that the TA be modified to distinguish between test manufacturers and clinical laboratories offering LDTs to ordering physicians.**

While AMP respects the specific expertise represented by the authors from the Tufts Medical Center Evidence-based Practice Center, the absence of genetics and molecular-based medical expertise in this report is of great concern. Inclusion of subject matter experts as authors (or at least as editors) would not only help ensure that the document is a comprehensive survey of currently available tests, but also would fulfill the most rudimentary requirements of such a survey, *e.g.*, differentiating genetic from non-genetic tests. **AMP respectfully requests that the authors include subject matter experts prior to the finalization of this report to improve its accuracy and completeness. AMP stands ready to offer assistance to AHRQ on this report and future reports on molecular diagnostics.**

Thank you very much for the opportunity to comment on this draft TA and we hope these comments improve the document, enhance its utility and assist AHRQ in putting out the highest quality educational instrument. AMP offers its assistance as AHRQ moves forward on this and other technology assessments.