



**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)

## **The Association for Molecular Pathology Principles for Health Care Reform – June 2009**

Laboratory medicine is a critical and integral component of the nation's health care infrastructure. Without clinical laboratory testing, it is impossible to accurately diagnose disease, monitor response to therapy or assess the status of chronic diseases. Accurate information from laboratory testing is central to the promise of personalized medicine as it allows appropriate utilization of targeted therapies. Laboratory tests are also a high value component of the health care system, comprising a small percentage of health costs but delivering information that informs 60-70% of treatment decisions.

Members of the Association for Molecular Pathology (AMP) are developing increasingly sophisticated molecular tests for a wide spectrum of clinical applications on a near-daily basis. These tests are the embodiment of "translational medicine," that is, they are the pathways through which information learned in basic genomic research then becomes molecular tools for the improvement of human health. Tests performed in the laboratories of AMP members have had a significant impact on the understanding and treatment of chronic conditions such as HIV, cancer, heart disease, diabetes, inherited genetic diseases and many others. Looking ahead, many of these tests and those yet to be developed will be instrumental in making medicine more predictive, preventive and cost effective.

AMP supports efforts to achieve comprehensive health care reform, to make the health care system more efficient and to improve the quality of patient care. Consistent with these goals, AMP encourages Congress and President Obama's administration to adopt measures that will strengthen the practice of laboratory medicine and the availability of laboratory tests to patients. Specifically, AMP encourages the adoption of the following principles:

### **I. Clinical laboratory testing should be part of the covered benefits in all health plans.**

Without laboratory testing, accurate diagnoses cannot be made, effective treatments cannot be chosen, and disease progression and response to therapy cannot be monitored.

#### **AMP recommends:**

1. Health systems should encourage appropriate utilization of clinical laboratory services by compensating health care providers who institute molecular tests consistent with consensus clinical guidelines.
2. Medicare beneficiaries should continue to have full access to clinical laboratory services without co-payments in order to encourage prevention, early diagnosis and wellness.

### **II. Clinical laboratory tests should receive appropriate reimbursement commensurate with the added value and savings they contribute to health care delivery.**

While clinical laboratory tests comprise less than 5% of hospital costs and about 1.6% of all

Medicare costs, their findings influence 60-70% of health care decisions. Molecular tests account for a far lower proportion of health care costs than clinical laboratory tests as a whole. Yet, such tests are at the core of “personalized medicine.” Therefore, molecular tests are likely to offer even greater value than routine clinical laboratory tests in the future.

**AMP recommends:**

1. Health plan payment systems should provide appropriate reimbursement for molecular tests. Existing mechanisms should be reviewed for accelerated ways to consider new and useful molecular tests for billing codes and coverage decisions.
2. The clinical laboratory community and payers should work together to devise a coding system for molecular diagnostic assays that provides for greater simplicity and uniformity in coding. An important structural objective of such a system would be to resolve current problems encountered where coverage for legitimate assays which require the use of universal procedural CPT codes is inadvertently denied because policies restrict such codes to a limited set of disease-related ICD-9 codes.
3. Medicare reimbursement for clinical laboratory services and their interpretation should receive regular Consumer Price Index (CPI) updates. When Congress established the Medicare fee schedule for clinical laboratory services, it capped payments and promised that those payments would keep pace with inflation by authorizing annual inflation updates. Updates have more often than not been eliminated or reduced to less than inflation.
4. Clinical laboratory services should continue to be direct billed to payers. Bundling of laboratory services with hospital or physician payments potentially creates incentives for reduced use of clinical laboratory services which could compromise optimal patient care.

**III. Comparative Effectiveness Research (CER).** Not surprisingly, policy makers are looking to determine the most effective manner to balance the cost of tests and treatments with patient care outcomes. As molecular-based laboratory tests are considered in this matrix, it is vital to strike the right balance between the short-term considerations of cost and the longer term value of these tests in optimizing patient care.

**AMP Recommends:**

1. **Infrastructure.** Infrastructure should be developed to design a model and process for CER regarding clinical laboratory tests. This should include the following:
  - The creation of a panel of experts consisting of physicians and scientists, particularly those with practical experience in the fields of molecular pathology and molecular diagnostics, economists, and reimbursement specialists.
  - Creation of an electronic clearinghouse for information on CER projects similar to [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Reliable tracking and coordination of CER activities will be crucial to avoid duplication and redundancy and to ensure appropriate use of CER funds. An investment in an effective tracking system will be a key component of any CER infrastructure in the United States. Moreover, access to

the tracking data should be available to all entities conducting CER, both from the private and public sectors.

- Development and adoption of standards for the collection and storage of data from molecular testing laboratories for archiving the results and facilitating interoperability between databases to assist with tracking and coordination of CER activities. Moreover, these databases should include information on the reason for the test, the type of test, test results and availability of genetic counseling and testing centers.
- Data from technologies and tests being assessed should be generated only by CLIA- or CAP-certified laboratories or ISO- or FDA-certified institutions. Consulting with or recruiting professionals from the molecular pathology community to serve on CER assessment committees will aid in evaluating the quality of proposals and the data generated.

**2. Clinical Outcomes in Genetic Testing.** As information becomes available that relates clinical outcomes to genetic variations, the regulatory, medical and lay communities expect that it will be immediately incorporated into routine clinical care. FDA labeling that relates pharmacogenomic data to clinical response and drug dosing, for example, has created demand for both testing and reimbursement in the absence of large clinical trials that demonstrate the effectiveness of such laboratory testing by comparison with either “usual care” or alternative approaches. Unlike drugs and implantable medical devices, clinical laboratory tests typically serve as a single input in a complex medical decision making process. Thus, the impact of clinical laboratory tests on clinical outcomes is far less direct than pharmaceutical products and therapeutic devices, and much more difficult to measure. Funding for large, carefully designed comparative effectiveness trials for clinical molecular tests should be coupled with funding for observational comparative effectiveness studies of patients who may be tested, but do not necessarily meet the inclusion criteria for prospective trials. Moreover, in recognition of the limited knowledge of how best to evaluate the clinical utility of laboratory tests, the results of such studies must be viewed flexibly and in the context of their limitations, when coverage decisions are considered. Finally, It should be noted that in the case of some rare genetic diseases, large scale, randomized case controlled studies simply aren't feasible due to the relatively small patient population.

- 3. Evaluating the Effectiveness of Genomic Tests and Clinical Laboratories.** For the public to reap the benefits of effective molecular tests, it is critical that clinical laboratories meet high performance standards, with appropriate reference and control materials. This can be achieved by:
- The provision of funding for a program to develop reference materials, exploiting traditional and innovative methodologies, to aid the continued advancement of quality measures in the field of laboratory medicine.
  - The development of novel proficiency testing methods as alternatives to distributing surrogate specimens to testing laboratories. For instance, in

cytogenetics it is impossible to send out surrogate specimens for every known translocation and rearrangement. Categorical methodologic proficiency testing should be evaluated as one such alternative.

**IV. Preventive and early diagnostic laboratory services are a critical component of true health reform and should be covered in all health plans.** A key tenet of health care reform must be to elevate the importance of screening, wellness and prevention programs. This would result in significant savings to the health systems and a better quality of life for millions of Americans.

**AMP recommends:**

1. Out-of-pocket costs (co-pays or deductibles) for screening and prevention laboratory tests should be limited.
2. Reformulate, enhance and empower the US Preventive Services Task Force (USPSTF) to adopt revised adult screening guidelines. Membership on the USPSTF should be expanded to include specialty physicians, public health professionals, laboratory professionals with screening test expertise, epidemiologists, and biostatisticians. This expanded body should consider evidence consensus clinical guidelines from professional medical groups and peer reviewed literature in addition to research studies.
3. Establish a separate Working Group for USPSTF for the advancement of innovative molecular-based screening test guidelines. Membership in this Working Group would ideally include expertise from a wide range of agencies and professional associations with in-depth knowledge of screening tests.

**V. Balanced Regulation and Oversight.** Efforts to enact health care reform should accelerate personalized medicine with a simultaneous commitment to regulatory balance that will allow progress and innovation in clinical laboratory testing to continue and not place needless burdens on this now well-regulated practice.

**AMP recommends:**

1. Broadening the inter-agency coordination between the Centers for Medicare and Medicaid Services and the Food and Drug Administration.
2. Utilizing CLIA as the regulatory authority for clinical laboratory services.
3. Avoidance of overlapping and potentially conflicting regulatory requirements that impede innovation.
4. Allowing for a participatory approach that draws on the expertise of all industry stakeholders.