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Special Article

Oversight of Genetic Testing: An Update

From the Editor

Our world is changing, and our field is changing with it. Each new advance in technology, each new application, each step forward in automation and reduction in time and work required to perform molecular testing expands the potential of molecular diagnostics to impact the clinical management of patients and their families. The completion of the Human Genome Project will propel our field forward rapidly, and has already had a major impact in raising the visibility of our field in the public eye.

Concomitantly, we have become more visible to government and regulatory agencies as well. Many of you have carefully followed the discussions of the Food and Drug Administration (FDA) over the years, and more recently the deliberations of the Secretaries Advisory Committee on Genetic Testing (SACGT) and the Clinical Laboratory Improvement Advisory Committee (CLIAC). Both groups have been at work these past two years, discussing the means by which genetic testing should be ordered, performed, reported, and overseen in the United States. Obviously, the results of their discussions would have enormous implications for those involved in molecular diagnostics.

The primary concern leading to the establishment of SACGT approximately two years ago was protection of the public from harm due to inappropriately used or performed genetic testing. SACGT is a federally mandated group acting under the auspices of the Secretary of Health and Human Services. They hold that increased oversight of genetic testing is necessary, particularly since much of genetic testing is currently done via methods developed by individual laboratories and not by FDA-approved kits, and have recommended that the FDA be the agency to provide this oversight. In their deliberations, the definition of genetic test is very broad and would include both somatic and germline alterations. They have worked to develop a mechanism by which tests could be stratified based on their intended use and potential impact on patient care. In theory, this would allow triaging of "high-risk" tests such as those for Huntington's disease or BRCA1 into a high scrutiny category necessitating high level oversight, whereas less critical tests such as Factor V Leiden, for example, would require a lower intensity scrutiny. Such algorithms have thus far proven unwieldy and ineffective for risk stratification, however, in part due to the multiple intended uses for many of these assays (disease confirmation, prenatal assessment, carrier detection, population screening, etc) and thus are still under discussion. SACGT holds firmly that some sort of FDA approval mechanism is needed before these tests can be applied to clinical decision-making.

Numerous professional groups have responded to SACGT and have worked with the FDA through the FDA-Professional Organization Roundtable discussions in an effort to help develop a practical oversight plan. Many of these groups, including the Association for Molecular Pathology (AMP), hold that existing mechanisms for laboratory accreditation and oversight are best suited to be the nidus for any new oversight programs. Laboratories performing clinical testing must currently be certified by the College of American Pathologists (CAP) and Clinical Laboratory Improvement Act (CLIA). Inspection and accreditation of laboratories by CAP provides a very detailed assessment of laboratory and quality control practices in molecular diagnostics laboratories. For example, laboratories are required to keep on file details and data of validation studies for each assay performed. CLIA requires additional quality-oriented practices. At the FDA Roundtable discussions, a genetic "template" was developed that could be used to help gather data on the use, performance, interpretation, and reporting of a genetic test. The template was very well received by SACGT, and discussion is underway regarding utilization of this template. The template would certainly help to gather and organize information on genetic testing and detailed laboratory practices, but numerous questions remain unanswered regarding further benefits of implementing use of the template. Would this move truly improve the quality of genetic testing in the United States, and in doing so, protect the public? Or would it duplicate existing regulatory mechanisms such as CAP accreditation, add to the administrative burden and cost of the labs, and thus limit public access to genetic testing? The views of AMP were presented at the most recent SACGT hearing in May 2001 by Dr. Debra Leonard, Past-President of AMP; her comments follow this introduction.

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Another federal group active in this arena is CLIAC. CLIAC has focused on defining genetic testing and addressing pre- and postanalytic issues in genetic testing, such as informed consent and reporting of results. Of note is that the definition of a genetic test put forth by CLIAC is extremely broad, to include not only nucleic acids but also proteins and metabolites. The recommendations of CLIAC are discussed in more detail by Dr. Andrea Gonzalez, Chair of the AMP Policy Committee, in the update to follow.

During the coming months, much will become clear with these various regulatory issues. I anticipate that we will be satisfied with some aspects of the increased oversight, and very dissatisfied with others. Regardless of the outcomes, we will have to find ways to live with the recommendations of these committees. In the meantime, we must remain actively involved, commenting and working with federal agencies when possible to effect workable solutions. In the end, better patient care is the goal for all of us.

Karen L. Kaul
Senior Editor

Statement by the Association for Molecular Pathology to the Secretary's Advisory Committee on Genetic Testing (SACGT), Presented May 2, 2001

Dr. McCabe and Members of the Committee:

Thank you for the opportunity to provide comments on the genetic test review template and review process. My name is Debra Leonard. I am an Associate Professor of Pathology and Laboratory Medicine and Director of the Molecular Pathology Laboratory at the University of Pennsylvania. I have medical training and am board-certified in Pathology and have doctoral and postdoctoral training in molecular biology. I am here today as the Past President of the Association for Molecular Pathology. AMP is a society of more than 600 medical professionals engaged in the practice of laboratory testing for human molecular diagnostics, as well as translational research in molecular pathology, molecular medicine, and molecular genetics. Many of our members are physicians or doctoral scientists who direct clinical diagnostic laboratories that perform molecular genetic testing. Therefore, the changes this Committee is recommending for oversight of genetic testing are of great interest and concern to the members of AMP and to me.

I asked to speak to you today because I have taken an active role in meetings between the Food and Drug Administration (FDA) and professional organizations, which resulted in the development of the genetic test review template. I would like to emphasize that AMP chose to work closely with the FDA not because we are in agreement with the proposed FDA oversight of genetic tests, but because we want to have input into changes that will greatly affect our membership, if they are implemented. The review template is an outline of information needed to assess the analytical characteristics, test reports, quality assurance programs and clinical validity and interpretation for genetic tests. This review template is thorough and represents an excellent guideline for laboratories developing, validating and performing any type of clinical test, not just genetic tests. During the meetings between the FDA and professional organizations, this review template was developed with the intent of augmenting the existing clinical laboratory inspection process administered by Health Care Financing Administration (HCFA) under the authority of the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), since time for review of test development and validation is limited during these inspections. However, the mandatory requirement to submit this information for all in-house developed tests by all clinical laboratories in the United States will be an administrative nightmare for both the laboratory and the reviewing agency. The proposed FDA oversight of genetic testing is redundant with existing regulations that already provide sufficient oversight of clinical laboratory testing, through HCFA and professional organizations like the College of American Pathologists and the American College of Medical Genetics. AMP is concerned that the proposed additional oversight by the FDA will greatly increase the administrative burden for laboratories, delay implementation of new tests due to review delays, limit patient access to genetic tests, and increase testing costs without improving the quality of genetic testing services. If this Committee does move forward with the implementation of genetic test review using this template, AMP strongly suggests incorporation of the template into the existing clinical laboratory inspection process administered by HCFA under the authority of the CLIA '88, rather than creating a new regulatory process.

As with all clinical laboratory test services, AMP believes that guidelines for the performance, interpretation, and clinical use of genetic tests are best established with primary input from medical and laboratory professionals who have the required expertise to judge the accuracy and validity of each test. AMP welcomes the support and facilitation by government agencies of professional efforts to establish genetic testing guidelines and standards through the establishment of a genetic testing consortium. AMP is eager to work with other professional organizations and government agencies to formulate professional standards for genetic testing.

I would like to address one additional point. AMP remains very concerned with the broad definition of "genetic tests" being used by this Committee, which includes testing for both inherited and acquired disorders. Acquired changes in the DNA of non-germline cells, such as occurs in cancer cells, are not inheritable. Most of the issues raised by genetic testing focus on the ethical and social concerns surrounding genetic testing, such as informed consent, genetic counseling, and implications of test results for other family members. Tests for acquired mutations, although potentially complex in performance and interpretation, raise no more concern than other diagnostic laboratory tests. Appropriate regulations for acquired disease testing already exist in the CLIA

regulations. If this Committee's concern is the fact that both types of testing are developed by laboratories, without the use of commercially produced and FDA-reviewed test kits, then this issue should be addressed separately from genetic testing issues. Applying genetic testing requirements to acquired disease testing is not only unreasonable, but will create problems for laboratory implementation. The bottom line is that a genetic test has to be defined based on inheritance, not on the fact that nucleic acids are used as the testing material. We urge you to narrow the definition to include only testing for germline inheritable genetic disorders.

In summary, AMP asks this Committee to work through the existing regulatory agencies and mechanisms for inspect ion and licensing of clinical laboratories to achieve any additional oversight specific to genetic testing that it deems necessary. The addition of another regulatory agency for genetic testing oversight is unnecessary, since existing regulatory mechanisms for clinical laboratories already assure the high quality of laboratory testing we have today.

Thank you again for this opportunity and for your attention.

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FDA Working Draft: Generic Genetic Test Review Template

1. Name of test
2. Intended use of test (What does the test measure?)
3. Indications for use of test
   a. Disease or condition testing for:
   b. Purpose or uses of test (for example, diagnostic, prenatal, presymptomatic, prognosis, minimal residual disease monitoring, etc.)
   c. Target population (for example, children, adults, African Americans, Ashkenazi, stage II breast cancer patients, etc.)
4. Method category (e.g., new methodology, PCR-RFLP with Southern hybridization, RT-PCR with gel analysis, trinucleotide repeat by PCR or Southern, protein truncation, etc.)
5. Methodology (create specific templates for each category of method)
   Submit Procedure Manual for reference
   Example of RT-PCR method information
   Specimen type(s)
   Specimen handling
      Prior to laboratory
      By laboratory
      Maintenance of specimen
   Test reagents
   RNA extraction method
   RNA storage and maintenance
   RT method
   Primers
      Published
      Designed by laboratory
         Method used
         Characteristics of primers
      Location of primers relative to purpose of test
      Size of RT-PCR product
   PCR reaction conditions and cycling parameters
      Published
      Optimization analysis performed by laboratory
   RT-PCR product analysis method
   Controls: preparation and use
      RNA degradation control method
      Positive control
      Negative control
      Sensitivity control
      PCR contamination control (including DNA contamination control)
      Other
   Expected results and calculations
   Technical interpretation of test results: positive, negative, inconclusive
6. Submit examples of test results
7. Analytical validity
   a. Control specimens
      Type
      Where obtained (IRB-approved or waived study: hospital or clinic, normal population, tissue bank (anonymous))
      Positive or negative control
      Results with test
   b. Number of specimens tested/ethnicity of specimen
   c. Types of specimens tested
      Specimen types (e.g., blood, CSF, tissue types etc)
      Expected positive specimens
      Expected negative specimens
   d. Results
      Results for specimens tested
      Sensitivity
      Specificity
      Accuracy
      Reproducibility or precision
      Other
   e. How were results confirmed?
      Run in duplicates
      Comparison to another test method
      Proficiency panel exchange with another laboratory
      Other
   f. Statistical analysis
8. Quality control procedures
   a. External controls
   b. Checks of results
   c. Repeat specimens
   d. How does interpretation of controls affect interpretation of test results?
   e. Frequency of quality control assessments
9. Clinical validity (choose A OR B)
   a. Literature citations and summary specific to test method
   b. Study results and summary
      Sensitivity
      Specificity
      Negative predictive value
      Positive predictive value
   c. Additional influences potentially affecting manifestation of disease and test interpretation (can cite literature)
      Penetrance
      Expressivity
      Anticipation
      Other (polymorphisms, environmental/lifestyle factors)
10. Clinical interpretation
   a. Submit report templates or examples of reports for all expected results
      Reports should be complete according to regulatory requirements and include:
         Interpretation by test purpose
         Strength of association of result with disease or disease risk
   b. Information used for risk assessment calculations

11. Limitations
    a. Technical
    b. Biological
12. Clinical utility, if available or known
    a. What interventions are available to an individual with a positive test result?
    b. What is the level of efficacy of such interventions?

Increased Oversight of Genetic Testing and CLIA'88

The Clinical Laboratory Improvement Act of 1988 (CLIA'88; Public Law 100–578) was enacted as the result of public and congressional concern with regard to the quality of laboratory testing in the United States.[1] The new regulation superseded CLIA'67 and provided standards designed to improve the quality of laboratory testing. In addition, CLIA'88 expanded federal oversight to include almost all laboratories performing testing on human specimens for the purposes of diagnosis, prevention or treatment of a disease. It is important to point out that laboratories performing research are not subject to CLIA'88 unless the research laboratory provides test results to the individuals tested, their families and/or treating physician. CLIA'88 regulations apply whenever the latter occurs, even if there is a disclaimer in the final report that states that the test results should be used for research purposes only or there is no charge for the test. CLIA'88 provides specific standards applicable to all areas of the testing process including personnel training, proficiency testing, quality control, and quality assurance. The legislation and associated regulations establish a system of registry as well as sanctions and enforcement procedures to ensure that the standards established by the federal regulation are maintained. The regulations for implementing CLIA'88 were developed by the Department of Health and Human Services through the Public Health Service. The Center for Disease Control and Prevention (CDC) was assigned to categorize tests according to the complexity of the various tests for analyses, and supervise implementation of standards. Recently, this responsibility has been transferred to the FDA. The FDA was assigned to review and guarantee the safety and efficacy of tests and the Health Care Finance Administration was to collect fees, issue permits, survey laboratories and initiate punitive actions when necessary.

Laboratory practices are divided into categories. The categories are Microbiology, Serology, Chemistry, Hematology, Immunohematology, Pathology, Radiobioassay, Histocompatibility, and Cytogenetics. Under CLIA'88, tests are categorized as waived, provider-performed microscopy, moderate complexity and high complexity. A numeric score system was developed to classify tests into moderate and high complexity. The scoring system takes into account some of the following criteria: knowledge required for performing the test, training and expertise, availability of calibrators, quality control, proficiency testing, operational characteristics, degree of interpretation and judgment, etc. A test is considered of moderate complexity when it receives a score of 13 or less. Anything above a score of 13 is considered highly complex. Clearly, genetic tests and all molecular diagnostic tests for that matter are considered high complexity testing. In addition, the Health and Human Department established an advisory committee named Clinical Laboratory Improvement Advisory Committee. CLIAC membership consists of individuals that provide, use and develop laboratory services. This committee provides advice on technical and scientific aspects of the stipulation of CLIA'88 to the secretary of Human and Health Department. In addition, specialized subcommittees or workgroups could be established to review specific issues and provide advice and/or specific recommendations to CLIAC.

When CLIA'88 was enacted, genetic testing was in its infancy and had not become a defined specialty. More recently, concerns about the need to develop a genetics specialty have been raised. As part of the Human Genome Project, the National Institute of Health and the Department of Energy established a joint Working Group on the Ethical, Legal, and Social Implications (ELSI Working Group). In 1995 ELSI established a Task Force on Genetic Testing as concern about the ethical, legal, and social implications of the human Genome Project grew in the community. The Task Force was charged with assessing the status of genetic testing in the United States and making recommendations to ensure the development and implementation of safe and effective genetic tests. In 1997 the NIH/DOE Task Force on Genetic Testing published their final report titled "Promoting Safe and Effective Genetic Testing in the United States" (http://www.nhgri.nih.gov.ELSI/TFGTfinal/). In the report the Task Force recommended that the CDC create a Genetic Working group of CLIAC to consider the need for a genetics specialty under CLIA. As already mentioned, even though genetic testing meets the definition of testing under CLIA, there is neither a specific category for genetic tests nor specific requirements for genetic testing. In 1998, CLIAC recommended the creation of a Genetic Workgroup (GW) to consider the need for creating a new genetic specialty under CLIA'88. The GW was charged with assessing the applicability of CLIA with respect to preanalytic, analytic, and postanalytic phases of human genetic testing, and determining if new regulations were required to assure that genetic tests are safe and effective before use. CLIAC endorsed the recommendations provided by the GW on how CLIA regulations could be modified to address genetic testing

In May 2000 the CDC published in the Federal Register a Notice of Intent (NOI) to advise the public of a plan by the Department of Health and Human Services through issuance of a Notice of Proposed Rule Making to revise CLIA regulations with regard to human genetic testing.[2] In response to the NOI, the CDC received a total of 57 letters with more than 800 comments from professional organizations, individuals, State and Federal agencies and manufacturers. After review of public responses, the CDC presented a summary of the public comments to CLIAC. CLIAC recommended the creation of another GW to evaluate the responses to the NOI and provide input to assist CLIAC in making further recommendations. The

GW evaluated the responses to the NOI and developed recommendations that were presented at the February CLIAC meeting. The following are some of the recommendations presented to CLIAC:

Genetic Specialty

The GW recommended the development of a specialty in genetics that will include heritable and acquired mutation testing. This specialty will include three subspecialties: molecular genetics, cytogenetics and biochemical genetics. The GW agreed that heritable mutation tests and acquired mutation test should have different requirements for pre- and postanalytic phases. Moreover, it might be necessary to further subdivide the subspecialties into diagnostic, predictive, and prenatal testing. The Work Group also recommended three new definitions for genetic tests, one for each subspecialty. The new definitions are as follows:

1) *Molecular genetic test:* "An analysis performed on human DNA, RNA to detect heritable or acquired disease-related genotypes, mutations, phenotypes for clinical purposes. Such purposes would include predicting risk of disease, identifying carriers, and establishing prenatal or clinical diagnoses or prognoses in individuals, families, or populations";

2) *Cytogenetic test:* "An analysis performed on human chromosomes to detect heritable or acquired disease-related genotypes, mutations, phenotypes, or karyotypes for clinical purposes";

3) *Biochemical genetic test:* "The analysis of human proteins and certain metabolites, which are predominantly used to detect inborn errors of metabolism, heritable genotypes, or gene products of genetic variations or mutations for clinical purposes".

One can anticipate the difficulties that might be encountered when using these definitions to distinguish genetic from non-genetic tests. Hopefully, additional discussions in this particular issue will to set the requirements to the appropriate level.

General Requirements

Individuals Authorized to Order Genetic Tests

The current CLIA statute, which defers to state laws to define individuals who are authorized to order clinical tests, remains acceptable. There should not be federal requirements superseding state regulations in this matter. Self-referral is acceptable if the state law allows such ordering and the laboratory medical director accepts responsibility for not only ordering the test but also provide the appropriate level of informed consent. In addition, ordering of predictive tests should not be limited to genetic professionals. The workgroup supported the NOI with regard to obtaining clinical information on the test requisition, but the Workgroup determined that the ordering physician should be responsible for providing appropriate demographics and clinical information. Shown in Table 1 is a list of information to be required in test requisitions. In addition the laboratory should provide guidance in deciding if additional or reflex testing is recommended.

Table 1. Information Required in Test Requisitions

Patient name
Date of birth
Time and date of specimen collection
Gender
Race/ethnicity (if applicable)
Unique identifier in specimen container
Specimen type (blood, amniotic fluid, etc.)
Reason for requesting the test
Relevant clinical or laboratory information
Pedigree (where applicable; require for linkage analysis)
Referring physician, health professional or other authorized to prescriber
Check-off box to indicate if appropriate level of informed consent has been obtained
Check-off box to indicate if patient has decline having his/her samples used anonymously for QA/QC purpose

Informed Consent and Confidentiality

The Workgroup recognized that all testing required informed consent but recommended that genetic testing might require different *levels* of informed consent. Levels of informed consent could be derived from established professional standards/guidelines. The individual ordering the test is responsible for obtaining the appropriate level of informed consent and the laboratory should be available to assist or provide guidance in determining the appropriate level of informed consent. As stated in Table 1, documentation for obtaining informed consent from the person ordering the test could be achieved by placing a check box and/or a line for signature in the test requisition form. For tests that require high levels of informed consent, the consent form should include information with regards to analytical and clinical validity and clinical utility as well as aspects of personal, social and family impact of tests results. In addition, during the informed consent process the individuals should be asked for approval or provide an op-out option with regard to the subsequent use of their anonymized samples for QA/QC purposes. Further use of specimens for research testing should be performed only under IRB-approved protocol with new consent. With regard to confidentiality, the Workgroup felt that CLIA currently addresses issues of confidentiality for all testing and these are sufficient for genetic testing.

Test Report

The person with the appropriate qualification must sign reports and for inherited disease testing, at least one person signing the report must be board certified in medical genetics. Shown in Table 2 is a list of elements that should be included in all reports. The Workgroup recognized that record retention should be a compromise between optimum time and clinical practicality. It

Table 2. Information Required in Test Reports

Name of individual
Date of birth
Time and date specimen collection
Time and date specimen receipt in the laboratory
Specimen accession number or case number
Race/ethnicity (where applicable)
Indication for testing
Test performed, including mutations tested
Test result
A statement interpreting the test result that include clinical implications and follow-up test, recommendations and/or genetic counseling indications
Documentation if preliminary reports has been issued
Notation of any deviation from laboratory standard practice
Signature from laboratory director and other authorized individual
Date of report
Mean to contact laboratory director or designee

was recommended that record be retained for at least 10 years.

Personnel Standards

Laboratory Director: According to the proposed laboratory standard a laboratory director must meet at least one of the following qualifications: 1) be an MD or DO or DPM with certification in clinical and/or anatomical pathology; 2) be an MD, DO or PhD and be certified by a board approved by HHS; 3) be an MD or DO and have two years of experience directing or supervising high complexity testing; 4) hold a doctorate degree in a chemical, physical, biological, or clinical laboratory science, be certified and have two years of experience in high complexity testing; 5) be grandfathered.

Technical Supervisor: 1) be an MD or DO with certification in clinical and/or anatomical pathology in addition to two years subspecialty training in genetics and have two years supervisory experience in high complexity genetic testing, or have four years supervisory experience in high complexity genetic testing in the relevant subspecialty; 2) be an MD, DO, or PhD and be certified in the appropriate medical genetics specialty and have two years of experience directing or supervising high complexity genetic testing in the relevant subspecialty; 3) hold a doctorate degree in a chemical, physical, biological, or clinical laboratory science, and have four years of training or supervisory experience in a high complexity laboratory in the relevant subspecialty; 4) be grandfathered.

Clinical Consultant: 1) be an MD, DO, and have two years experience in genetic testing; 2) hold a PhD in a relevant discipline, be board certified, and have two years experience in genetic testing.

General Supervisor: 1) be qualified as a laboratory director or technical supervisor; 2) be an MD, DO; 3) hold a doctorate or master's degree in a chemical, physical, biological, or clinical laboratory science, and have two years experience in high complexity genetic testing; 4) hold a baccalaureate degree in a chemical, physical, biological, or clinical laboratory science and have three years of experience in high complexity genetic testing; 5) be grandfathered. The GW recognized that the General Supervisor should have competency for the tests performed in the laboratory.

Testing personnel. No change from current CLIA regulation.

Genetic Counseling

The Working Group agreed that genetic counseling is not necessary for all genetic testing. Genetic counseling needs to be available but it should not be the responsibility of the laboratory to provide this service. Laboratories should be required to recommend genetic counseling when indicated.

Quality Control

Appropriate general quality control requirements must be developed for the genetics specialty as well as specific requirements for each subspecialty. The GW determined that more specific requirements for in house developed assays are not needed and recommended to rely on professional and/or private organizations to establish specific standards. In a departure from the NOI that recommended separation of laboratory areas (RNA *vs.* DNA areas), the Group felt that there is no need to federally require separation of the laboratory into different areas.

The clinical validity of a test needs to be defined for each test. The Laboratory Director will be responsible for documenting the clinical validity of a genetic test that the laboratory plans to offer. This responsibility could be delegated but ultimately the Laboratory Director will be responsible for ensuring the clinical validity of new test. The GW recognized that the definitions of clinical validity need to be clarified. During test validation, the number of positive probands that need to be included will be dependent on the disease, laboratory design, etc but it was also recommended to rely on professional organizations to provide guidelines/standards.

Proficiency Program

The GW recognized that interlaboratory exchange of samples is a useful alternative when an approved proficiency testing (PT) program for a specific test does not exist. There is a need to improve the quality of the current PT programs. The GW recommended a two-tier system with formal and interlaboratory comparison programs that are dependent in subspecialty, disease and technology. Due to some the difficulty encountered by current PT programs, it would be interesting to assess the usefulness of technology based versus disease-specific PT programs.

Specimen Retention

Specimen retention needs to be defined but the GW felt that the duration and format for specimen retention

would require additional input from end users as well as professional organizations. The GW recommended that specimens from individuals who refuse to have their residual specimens used for QA/QC purposes should be discarded according to laboratory policy.

CLIAC endorsed the majority of the recommendations of the GWG with minor modifications and recommended that the CDC continue to move forward with the development of a Notice of Proposed Rule Making that incorporates the new recommendations from CLIAC. The next step in this process will begin with the development of the proposed rule making for genetic testing by the CDC based on the revised CLIAC recommendations.

The proposed regulatory changes described here will certainly pose challenges to laboratories offering genetic testing at a time when resources are diminishing. Academic clinical laboratories will probably feel the greater impact. Will academic clinical laboratories be able to identify the resources that will be needed to comply with the proposed changes in CLIA, and at the same time continue to provide a fertile environment for the development, evaluation and implementation of new genetic testing? It is imperative that professional organizations and laboratories performing clinical genetic testing continue to voice their perspective in the hope to achieve a workable balance.

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References

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2. Notice of Intent; Genetic Testing under the Clinical Laboratory Improvement Amendments Notice of Intent. Federal Register 2000, 4:65(No. 87):25928–25934