Genetic Testing and the Clinical Laboratory Improvement Amendments of 1988: Present and Future

Morton K. Schwartz

Laboratory practice in the United States is regulated in many ways. The Food and Drug Administration (FDA), through the Medical Devices Amendment, controls new devices and attempts to insure their safety and efficacy. The Health Care Financing Administration (HCFA), through Medicare, controls reimbursement for laboratory tests, as do insurance companies. The Joint Commission for Accreditation of Health Care Organizations accredits hospitals, and thereby laboratory practice in hospitals. There is state and local legislation related to laboratory performance and the qualifications of practitioners. The ethics of clinical laboratory performance is essentially the responsibility of professional societies and consumer groups. The topic of this presentation is the role of CLIA ‘88, which regulates all laboratory practice in the United States, in genetic testing. CLIA regulations are mandated for a test performed on a specimen derived from the human body and whose analytical result is used in diagnosis or the management of a patient.

History of CLIA

CLIA ‘88 (Public Law 100-578) resulted from public and congressional concerns about the quality of clinical laboratory testing in the United States (1). The new regulations revised and superseded CLIA ‘67 and set standards designed to improve quality and to expand federal oversight to include virtually all laboratories in the United States that conduct testing on human specimens for health assessment or for the diagnosis, prevention, or treatment of disease. The regulations for implementing CLIA were developed by the Department of Health and Human Services (HHS) through the Public Health Service. The

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1 Nonstandard abbreviations: FDA, Food and Drug Administration; HCFA, Health Care Financing Administration; HHS, Health and Human Services; CLIA, Clinical Laboratory Improvement Advisory Committee; PT, proficiency testing; QC, quality control; QA, quality assurance; and DOE, Department of Energy.
CDC was assigned to categorize analytes and, in general, to supervise the implementation of the standards. The FDA was assigned to review and insure safety and efficacy of tests; the HCFA was assigned to collect fees, issue permits, survey laboratories, and initiate punitive actions where needed. There are four separate sets of CLIA rules: (a) standards, (b) application and fees, (c) enforcement, and (d) approval of accreditation programs. The rule on standards comprises most of the regulations with which laboratories must comply (Code of Federal Regulations, Section 176, Part 493, Title 42). The final regulations were published on February 28, 1992, and became effective on September 1, 1992, with some parts phased in over a period of time (2).

Under CLIA, laboratory practices are divided into the following categories: microbiology; diagnostic immunology; chemistry; hematology, including coagulation; pathology (histopathology, oral pathology, and neuropathology); cytology, cytogenetics; histocompatibility; and immunohematology (transfusion service). There is no genetics category (Table 1). Tests are categorized as waived, provider-performed microscopy, and those of moderate or high complexity. Waived tests are simple laboratory procedures that are cleared by FDA for home use, use methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible, or post no reasonable risk of harm to the patient if the test is performed incorrectly. Laboratories performing only waived tests must receive a CLIA certificate and follow the manufacturer’s instructions for the test, but are not required to implement other CLIA regulations. Provider-performed microscopy also requires only laboratory registration. These tests require use of a microscope and must be performed by a physician, dentist, or midlevel practitioner authorized by the state. These tests must be performed during the patient’s visit on a specimen obtained at that time. The classification of moderate-complex tests was based on an additive numeric score with a grade of 1 (least complex) to 3 (most complex) given to each of seven criteria. Scores below 13 were classified as moderate and those above as complex. The criteria used to classify tests were as follows: knowledge required to perform the test, the training of the user, complexity and experience required, characteristics of operational steps, availability of calibrators, quality control and proficiency testing material, troubleshooting and maintenance required, and the degree of interpretation and judgment. Originally, there were almost 12 000 analytes categorized (Federal Register 1993;58(141):39879). Since then, 3000 more have been added to the list (Federal Register 1996;61(131):35737).

The CLIA requirements to ensure quality testing include proficiency testing (PT), patient test management, quality control (QC), and quality assurance (QA). QA includes test ordering; availability of tests; patient preparation; collection and delivery of specimens; analytical performance, including turnaround time; data handling; interpretation of results; and clinical action by the user. QC requires preparation of procedure manuals, method calibration and validation, daily controls for each assay (at least two levels), adherence to manufacturer’s instructions, and written documentation of all QC activity. Patient test management involves rules to assure optimum integrity and identification of patient specimens throughout the testing process and result reporting. These rules identify requirements for specimen submission and handling, test requisitions, test records and reports, and the submission of specimens to other laboratories (2).

There are now ~158 000 laboratories registered under CLIA. Of these laboratories, 57% are physician office laboratories, 50% perform only waived tests, 20% perform provider-performed microscopy, and 11% (or almost 18 000 laboratories) are accredited to perform moderately and/or highly complex tests.

### Table 1. Laboratory testing under CLIA.

<table>
<thead>
<tr>
<th>Non-genetic testing</th>
<th>Genetic testing (proposed)</th>
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<tbody>
<tr>
<td>Microbiology</td>
<td>Molecular genetics-cytogenetics</td>
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<tr>
<td>Bacteriology</td>
<td>Human DNA, RNA, and chromosomes to evaluate genetic disease</td>
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<tr>
<td>Mycobacteriology</td>
<td>Biochemical genetics</td>
</tr>
<tr>
<td>Mycology</td>
<td>Analysis of certain human proteins and metabolites to evaluate genetic disease, primarily inborn errors of metabolism</td>
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<tr>
<td>Parasitology</td>
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<tr>
<td>Virology</td>
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<td>Serology</td>
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<td>Syphilis serology</td>
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<td>General immunology</td>
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<td>Chemistry</td>
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<td>Routine chemistry</td>
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<td>Endocrinology</td>
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<td>Toxicology</td>
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<td>Urinalysis</td>
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<td>Hematology</td>
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<td>Routine hematology</td>
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<tr>
<td>Coagulation</td>
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<td>Immunohematology</td>
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<td>ABO grouping and Rh typing</td>
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<td>Unexpected antibody detection</td>
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<td>Compatibility testing</td>
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<tr>
<td>Unexpected antibody identification</td>
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<tr>
<td>Pathology</td>
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<tr>
<td>Cytology</td>
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<td>Histopathology</td>
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<td>Oral pathology</td>
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<td>Radiobiocassay</td>
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<td>Histocompatibility</td>
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<td>Cyto genetics</td>
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</table>
Committee (CLIAC) to advise and make recommendations on technical and scientific aspects of the provisions of CLIA. CLIAC will be comprised of individuals involved in the provision of laboratory services, utilization of laboratory services, development of laboratory testing or methodology, and others as approved by HHS. Specialized subcommittees or work groups may be created by HHS as necessary and CLIAC or any designated subcommittee or work group will meet as needed, but not less than once each year.

CLIAC or subcommittees at the request of HHS, will review and make recommendations concerning: criteria for categorizing tests and review of analytes categorized as moderately complex and highly complex; determination of waived tests; personnel standards; patient test management, QC, QA standards; PT standards; applicability to the standards of new technology; and other issues relevant to CLIA if requested by HHS.

HHS will be responsible for providing necessary data and information to the members of CLIAC. Subcommittees and workgroups report to CLIAC who will either accept, reject or modify their recommendations”.

CLIAC was formed in February 1992, under a charter issued by the Secretary of HHS. The charter states that CLIA will provide scientific and technical advice and guidance to the Secretary and the Assistant Secretary for Health regarding the need for, and the nature of, revisions to the standards under which clinical laboratories are regulated, the impact on medical and laboratory practice of proposed revisions to the standards, and the modification of the standards to accommodate technological advances.

The committee consists of 20 members, including the Chair. Members are selected by the Secretary from authorities knowledgeable in the fields of microbiology, immunology, chemistry, hematology, and pathology, and representatives of medical technology, public health, clinical practice, and consumers. In addition, CLIAC includes three ex officio members, or designees: the Director, CDC; the Commissioner, FDA; the Administrator, HCFA; and such additional officers of the US government that the Secretary deems are necessary for the Committee to effectively carry out its functions. CLIAC will also include a nonvoting liaison representative, who is a member of the Health Industry Manufacturers Association, and such other nonvoting liaison representatives that the Secretary deems are necessary for the Committee to effectively carry out its functions. The members of CLIAC, as of July 1, 1998, are listed in Appendix 1.

Because of the diversity of its membership, it must be emphasized that CLIAC is at times divided in the guidance and advice it offers to the Secretary. Even when all CLIAC members agree on a specific recommendation, the Secretary might not follow their advice because of other overriding concerns. Thus, although some of the actions recommended by CLIAC may eventually produce changes in the law, the reader should not infer that all of the advisory committee’s recommendations will be automatically accepted and acted on by the Secretary.

Genetic Testing

At the time CLIA was written and when CLIAC was initiated, DNA-related genetic testing was in its infancy and had not yet become a defined laboratory specialty. Biochemical testing used in evaluation of genetic disease was considered part of chemistry. During the decade since its inception, DNA probe technology has been made part of those areas of CLIA where it is used (for example, microbiology, pathology, and histocompatibility). No special category for genetics was designed.

The proposed role of CLIAC in genetic testing was an outcome of several studies. The Human Genome Project was initiated in 1990 under the guidance of NIH and the Department of Energy (DOE). It is estimated that by 2005 most of the estimated 100 000 human genes will be identified and catalogued. Already there are clinical tests proposed for use in the screening and management of patients with genetic disease. During this period of exploding technology, there has been great concern not only about the legal, ethical, and social aspects of genetic testing, but also the quality of laboratory testing and the availability and access of these procedures during the rapid commercialization of the tests. In 1997, a joint NIH-DOE Task Force on genetic testing was established. In anticipation of recommendations from this Task Force a genetics work group of CLIAC was formed. The NIH-DOE Task force recommendation was as follows: “The Task Force urges the newly created Genetics Subcommittee of CLIAC to consider the creation of a specialty of genetics which would encompass all predictive tests that satisfy criteria for stringent scrutiny. If only a subspecialty for DNA/RNA-based tests is feasible, the subcommittee must then address how to assure the quality of laboratories performing non DNA/RNA predictive genetic tests. The agencies primarily responsible for administering CLIA; HCFA and CDC should take the lead in implementing these recommendations”.

In October 1997, the CDC, in response to a directive by Dr. David Satcher, who was then Director of the CDC, published a strategic plan for integrating advances in human genetics into public health action. The report entitled, “Translating Advances in Human Genetics in Public Health Action: A Strategic Plan”, reiterated the NIH-DOE recommendations and mandated CLIA to establish “standards, regulations and guidelines to ensure the accuracy, validity and precision of laboratory procedures and to ensure that other QA issues are addressed as well”.

CLIAC and its genetics working group were requested by HHS to review genetic testing. They concluded that CLIA should include a dedicated genetic testing section.
This conclusion was based on the fact that although the testing technology is similar to that used in other laboratory areas, the sensitivity of genetic testing results and the social, economic, and legal aspects of such tests requires a separate section in CLIA. It was felt that the high degree of precision and accuracy required for genetic testing required stringent regulations. Genetic testing was considered from the point of view of preanalytical, analytical, and postanalytical concerns. Current CLIA regulations were reviewed to determine which rules were applicable and where new rules to cover genetic testing adequately or additions or amendments to those now in place were needed. The following are the draft proposals of CLIA. These will require governmental review and approval and public comment before they are incorporated into CLIA.

Definitions

The genetics workgroup recommended to CLIA that two definitions of genetic testing are needed. These were modified and adopted by CLIA.

Molecular Genetic and Cytogenetic Test. The analysis of human DNA, RNA, and chromosomes to detect heritable or acquired disease-related genotypes, mutations, phenotypes, or karyotype for clinical purposes. Such purposes include predicting risk of disease, identifying carriers, and establishing prenatal or clinical diagnosis or prognosis.

Biochemical Genetic Test. The analysis of materials derived from the human body, including human proteins and certain metabolites predominantly used to detect inborn errors of metabolism, heritable genotypes, or mutations for clinical purposes. Such purposes include predicting risk of disease, identifying carriers, and establishing prenatal or clinical diagnosis or prognosis. [Tests that are used primarily for other purposes, but may contribute to diagnosis of a genetic disease (e.g., blood smears and certain serum chemistries), would not be covered by this definition.]

Confidentiality and Informed Consent

Because of the sensitive nature of certain genetic tests, the recommendation was that the laboratory should have a policy in place that deals with the confidential nature of test result reporting and defines who is authorized to order tests. According to CLIA [Code of Federal Regulations, Section 2: Definitions, Part 493, Title 42 (10-1-97 edition)], an “authorized person means an individual authorized under state law to order tests or receive these results or both”. The laboratory must have assurance that the authorized person has obtained appropriate informed consent from the patient. At the request of the authorized person, the laboratory shall assist in developing appropriate informed consent including limitations and consequences of the test result. The committee felt that a more explicit definition was needed for the words “authorized” and “appropriate”.

Personnel Standards

Laboratory director. According to the standards, a laboratory director must meet one of the following criteria:

- Be an MD or DO with certification in clinical and/or anatomic pathology; or
- Be an MD, DO, or PhD with certification in medical genetics. [This is a new proposal inserted into the current Laboratory Director Standard.]
- Be an MD or DO and have 2 years experience directing or supervising high complexity testing; or
- Hold a doctorate degree in chemical, physical, biological, or clinical laboratory science, be certified, and have 2 years of supervisory experience in high complexity testing; or
- Be grandfathered.

Clinical consultant (genetic testing; new section). A clinical consultant must meet one of the following criteria:

- Be an MD or DO, and have 2 years experience in genetic testing; or
- Hold a PhD in a relevant discipline, be board-certified, and have 2 years experience in genetic testing; or
- Hold an MS in genetic counseling, be board-certified, and have 2 years experience in genetic testing (prospective); or
- Be grandfathered. (The recommendation for grandfathering was deferred pending receipt of additional information.)

The responsibility of the laboratory director and the clinical consultant are to ensure that reports of test results include pertinent information required for clinical interpretation that is meaningful to a nongeneticist healthcare provider.

In addition, they must assist the individual who orders the test to understand what clinical information the test will yield and to recommend follow-up tests when appropriate.

Technical supervisor (genetic testing; new section). A technical supervisor must meet one of the following criteria:

- Be an MD or DO, with certification in clinical and/or anatomic pathology plus 2 years subspecialty training in genetics, and have 2 years supervisory experience in high complexity genetic testing or have 4 years supervisory experience in high complexity genetic testing in the relevant subspecialty; or
In addition to the general laboratory responsibilities for a technical supervisor now outlined in CLIA, the technical supervisor (genetics testing) must ensure that reports include pertinent information required for specific patient genetic testing.

The committee felt strongly that the primary responsibility for the day-to-day operation of a genetics laboratory would be in the hands of the technical supervisor. It was recommended that the title "Technical Supervisor" be changed to "Technical Director", not only for genetic testing, but for all laboratory specialties. This was proposed with an understanding that the title is appropriate for the level of responsibility required, that the General Supervisor may report to this title is appropriate for the level of responsibility required; that the title "Technical Director" is more reflective of the "real world".

General supervisor (genetic testing; new section). A general supervisor must meet one of the following criteria:

- Be qualified as a laboratory director or technical supervisor; or
- Be a PhD or DO; or hold a doctorate or masters degree in chemical, physical, biological, or clinical laboratory science and have 2 years experience in high complexity genetic testing; or hold a baccalaureate degree in chemical, physical, biological, or clinical laboratory science and have 3 years experience in high complexity genetic testing; or
- Be grandfathered.

Testing personnel. No change from current CLIA regulations [Code of Federal Regulations, Section 1489, Part 493, Title 42 (10-1-97 edition)].

QUALITY CONTROL

In addition to current CLIA regulations related to QC, the committee made the following specific recommendations for genetic testing: a specimen must be stabilized until clinical information for accurate testing is available; the information required before a test can be performed should include unique identification for the patient/subject, including date of birth, gender, ethnicity, patient or family members, laboratory number; clinical information required for test selection, and test interpretation; the name of the healthcare provider to whom results are to be reported as well as the name of the person obtaining sample; specimen type and source; preservation and transport; date/time specimen collected and received by the laboratory; and finally, any other information required for test assessment.

CONTAMINATION

The laboratory must be designed to minimize contamination. Amplification procedures not in wholly closed systems must separate preparatory steps from postamplification steps. Work processes must minimize risk of mixing samples and risk of contamination of equipment, reagents, or supplies. RNA work areas must be separated from DNA work areas.

PROFICIENCY TESTING

Whenever PT is available, laboratories must enroll and participate in programs commensurate with the test performed. The proficiency programs now available are listed in Table 2. None of these has yet been approved for CLIA purposes. When PT does not exist, the regulations should specify or reference the required alternatives. PT is to be performed three times per year on five specimens per event. Alternative methods for PT may include split samples sent to another laboratory in a blinded fashion or test samples assayed in duplicate in a blinded fashion by separate technologists. Other equivalent but undefined approaches may be used.

VALIDATION OF TESTS

The methodology must be appropriate for conditions/testing. Laboratories must establish reproducibility for each method within and between runs and between technologists and establish QC parameters as well as validate reagents. A positive confirmatory test must have a defined positive predictive value that can be communicated to the person who ordered the test. If applicable, the predictive value should be stated in terms of ethnic populations. When the disease prevalence is >1:10,000, the validity must be documented in at least 10 positive probands (including cell lines or DNA/RNA) before offering the test.

SPECIAL REPORTING REQUIREMENTS

The laboratory reports must include the following, as applicable: interpretation, comments, recommendations for further testing or clinical consultation, summary of the method and its limitation. In addition, the signature of the Director or the Director's designee must appear on the report as well as a means to quickly contact the Director. Any reference to family members must use standardized pedigree nomenclature or numeric indicators instead of individual names. For molecular genetic testing, the mu-
tant alleles tested must be listed with the detectable rate of the panel and, when required, a revised risk assessment. The report must include clinical implications for other family members and the variables, such as ethnicity, that affect test interpretation as well as the limitations of the test used.

RETORETENTION OF RECORDS
Reports of genetic testing must be retained for at least 10 years. Electronic records are acceptable. Specific regulations for specimen retention are not proposed, but each laboratory must have a written policy defining its own specimen retention policy.

REUSE OF TESTED SPECIMENS
There are valid reasons for a laboratory to retain tested specimens. These include test methodology improvement, confirmation of original diagnosis, use in QC or test development, and for educational and/or training purposes. CLIAC recommended that the reuse of samples when all identifiers are removed does not require informed consent. When identifiers are not removed, informed consent for their reuse must be obtained. When specimens are to be used without identifiers, there must be a mechanism to permit patients to elect to not have their specimens used.

**Conclusion**

It must be remembered that these are recommendations of CLIAC. This 20-person advisory committee was chartered in February 1992 to provide scientific and technical advice and guidance to the Secretary and the Assistant Secretary for Health regarding the need for and the nature of revisions to the standards under which clinical laboratories are regulated, the impact on medical and laboratory practice of proposed revisions to the standards, and the modification of the standards.

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Table 2. Available proficiency programs in genetic testing.

<table>
<thead>
<tr>
<th>Source</th>
<th>Tests offered</th>
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<tbody>
<tr>
<td>CAP&lt;sup&gt;a&lt;/sup&gt; American College of Medical Genetics</td>
<td>Karyotyping</td>
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<tr>
<td></td>
<td>CyF FISH chronic myelogenous leukemia</td>
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<td></td>
<td>CyG FISH-Williams syndrome</td>
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<tr>
<td></td>
<td>Urine or plasma for amino acid, mucopolysaccharide/organic acid, and material for specific metabolic disorders</td>
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<tr>
<td></td>
<td>Ethanol-fixed cell lines or extracted DNA: cystic fibrosis, factor V Leiden, DMOD/Becker, RhD, Prader-Willi/Angelman syndrome, Huntington disease, fragile X, and hemochromatosis</td>
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<td></td>
<td>Maternal screening (neural tube defects or fetal Down syndrome), α-fetoprotein, unconjugated estradiol, human chorionic gonadotropins for neural tube defects or fetal Down syndrome</td>
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<td></td>
<td>Leukemia and lymphoma gene rearrangement or selected translocations</td>
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<tr>
<td>CAP/Foundation for Blood Research</td>
<td>Karyotyping</td>
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<tr>
<td></td>
<td>Each laboratory must set up its own program for tests performed</td>
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<tr>
<td>CAP-Molecular Oncology</td>
<td>Serum or amniotic fluid α-fetoprotein</td>
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<td>Detection of chromosomal rearrangement, mutations in oncogenes, tumor suppressor genes</td>
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<td>Newborn screening of dried blood spots</td>
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<td></td>
<td>Thyroxin, thyroid-stimulating hormone, phenylalanine, methionine, total galactose, 17α-hydroxypregosterone, galactose-1-phosphate, uridytransferase, biotinidase, sickle cell anemia, α-thalassemia and hemoglobin F, cystic fibrosis under development</td>
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<tr>
<td></td>
<td>Karyotyping</td>
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<td>Serum and/or leukocyte pellets or sonicates for hexoseaminidase</td>
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<td>Organic and amino acids, including methylmalonic and glutaric acids as well as carnitine, homocysteine, lactate pyruvate, and fatty acids; purines, pyrimidines, mono- and disaccharides, and mucopolysaccharides</td>
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<tr>
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<td>Laboratory may select tests to make diagnosis</td>
</tr>
</tbody>
</table>

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<sup>a</sup> None of these has yet been accepted or recommended by CDC.

<sup>b</sup> CAP, College of American Pathologists; FISH, fluorescence in-situ hybridization.
to accommodate technological advances. It must be kept in mind that the Secretary may not follow the advice of CLIAC because of other overriding concerns. Thus, although some of the actions recommended by CLIAC may eventually produce changes in the law, it should not be construed that all of the advisory committee’s recommendations will be automatically accepted and acted upon by the Secretary.

References

Appendix 1: CLIAC, July 1998

Schwartz, Morton K., PhD
Chair

Baines, David R., MD
Benjamin, Regina M., MD
Bonfiglio, Thomas A., MD
Cada, Ronald L., Jr., MD
Charache, Patricia, MD
Gollin, Susanne M., PhD
Janzend, Verlin K., MD
Collins, Carilyn L., MD, MPH

Lifshitz, Aliza A., MD
Saigo, Patricia E., MD
Tillman, Ulder J., MD
Bowman, Lennard J., PhD
Burritt, Mary F., PhD
Madison, Bereneice M., PhD

Mass, Diana, MA, MT (ASCP)
McHugh, Deborah Reed, CRNP
Merlini, Toby L., MD
Price, Glenda D., PhD
Radford, Sharon V., MA
Segal, Elliott A., MPH

Gutman, Steve L., MD

Yost, Judith, MA, MT (ASCP)

Health Industry Manufacturers Association Liaison Representative

O’Neal, Wendell, PhD, Chair
The Whisk Group

Charache, Patricia, MD
Professor of Pathology Medicine
Oncology
Johns Hopkins Medical Institutions

Cox, David, MD, PhD
Professor of Genetics and Pediatrics
Department of Genetics M-33
Stanford University School of Medicine

Fisher, Nancy L., MD, MPH
Medical Director
Division of Health Services
Quality Support

Frias, Jaime L., MD
Lewis A. Barness Professor and Chairman
College of Medicine
University of South Florida

Ex Officio Officers

Genetic Testing Workgroup, July 1998

Merlin, Toby L., MD
Chief Medical Officer and Senior Vice President
Lovelace Health Systems
Pass, Kenneth A., PhD
Chief, Laboratory of Newborn Screening Genetic Services
Wadsworth Center for Laboratories
Rothstein, Mark A., JD
Director, Cullen Distinguished Professor of Law Health Law and Policy Institute
University of Houston
Gollin, Susanne, MD, PhD
Associate Professor of Human Genetics
Graduate School of Public Health
University of Pittsburgh
Ing, Paul Stephen, PhD
Cytogenetics
Boys Town National Research Hospital

Klinger, Katherine W., PhD
Senior Vice President
Genetics and Genomics
Genzyme Corporation
McCabe, Edward R.B., MD, PhD
Professor and Executive Chair
UCLA Department of Pediatrics
McGovern, Margaret, MD, PhD
Vice Chair
Department of Human Genetics
Mt. Sinai Medical Center
Schwartz, Morton K., PhD
Chairman, Department of Clinical Laboratories
Memorial Sloan Kettering Cancer Center
Silverman, Lawrence Mark, PhD
Professor of Pathology and Laboratory Medicine
University of North Carolina Medical School
Smith, Stephanie, MS
Division of Medical Genetics
University of Mississippi Medical Center

* It is with great sadness that I learned of Lem Bowie’s death on Christmas Day. Dr. Bowie was a close friend and a member of CLIAC. He was an energetic contributor during our discussion of the recommendations for genetic testing. He was always able to come up with recommendations and compromises that allowed us to proceed and develop this document. He will be sorely missed. This article is dedicated to his memory.