

**Clinical
Laboratory
Improvement
Advisory
Committee**

Summary Report

**March 2-3, 2011
Atlanta, Georgia**

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

**Clinical Laboratory Improvement Advisory Committee
March 2-3, 2011 Summary Report
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I. RECORD OF ATTENDANCE

Committee Members Present

Ms. Elissa Passiment, Chair
Dr. Ellen Jo Baron
Dr. Christine Bean
Ms. Susan Cohen
Dr. Judy Daly
Dr. John Fontanesi
Ms. Julie Gayken
Dr. Norman Harbaugh, Jr.

Dr. Paul Kimsey
Dr. Linda Sandhaus
Dr. Paula Santrach
Dr. Gail Vance
Dr. Emily Winn-Deen
Dr. Rosemary Zuna
Ms. Luann Ochs, AdvaMed (Liaison Representative)

Committee Members Absent

Dr. Stephen Raab

Executive Secretary

Ms. Nancy Anderson

Ex Officio Members

Dr. Alberto Gutierrez, FDA
Ms. Harriett Walsh, CMS
Dr. Devery Howerton, CDC

Designated Federal Official

Dr. Thomas Hearn
Dr. May Chu

Record of Attendance - cont'd.

Centers for Disease Control and Prevention (CDC)

Mr. Todd Alspach	Ms. Andrea Murphy
Dr. Rex Astles	Dr. James Peterson
Dr. Pawan Angra	Ms. Terri Phan
Ms. Diane Bosse	Ms. Cheri Rice
Dr. Tiffany Brunson	Dr. John Ridderhof
Dr. Roberta Carey	Dr. Shahram Shahangian
Dr. Bin Chen	Ms. Colleen Shaw
Dr. Maryam Daneshvar	Ms. Suzanne Seavello Shope, JD
Ms. Joanne Eissler	Mr. Darshan Singh
Ms. MariBeth Gagnon	Ms. Theresia Snelling
Mr. Albert Garcia	Dr. Susan Snyder
Dr. Amy Gargis	Ms. Heather Stang
Ms. Patricia Haskell	Dr. Shambavi Subbarao
Dr. Elizabeth Irvin-Barnwell	Dr. Julie Taylor
Mr. John Kastenbauer	Mr. Howard Thompson
Dr. Lisa Kalman	Ms. Pam Thompson
Dr. John Krolak	Ms. Irene Williams
Ms. Debra Kuehl	Dr. Laurina Williams
Dr. Ira Lubin	Ms. Yasmine Zavahir
Ms. Leslie McDonald	Dr. Barbara Zehnbauer
Dr. Anthony D. Moulton	

Department of Health and Human Services (Agencies other than CDC)

Ms. Sarah Bennett (CMS)	Dr. Linda Steel-Goodwin (AFIP, CCLM)
Dr. Jonathan Jarow (FDA)	
Ms. Penelope Meyers (CMS)	Ms. Sharon West (AFIP, CCLM)
Ms. Cathy Leppiaho (AFIP, CCLM)	

In accordance with the provisions of Public Law 92-463, the meeting was open to the public. Approximately 30 public citizens attended one or both days of the meeting.

II. Clinical Laboratory Improvement Advisory Committee

The Secretary of Health and Human Services is authorized under Section 353 of the Public Health Service Act, as amended, to establish standards to assure consistent, accurate, and reliable test results by all clinical laboratories in the United States. The Secretary is authorized under Section 222 to establish advisory Committees.

The Clinical Laboratory Improvement Advisory Committee (CLIAC) 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 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, pathology, and representatives of medical technology, public health, clinical practice, and consumers. In addition, CLIAC includes three ex officio members, or designees: the Director, Centers for Disease Control and Prevention; the Commissioner, Food and Drug Administration; the Administrator, Centers for Medicare & Medicaid Services; and such additional officers of the U.S. Government that the Secretary deems are necessary for the Committee to effectively carry out its functions. CLIAC also includes a non-voting liaison representative who is a member of AdvaMed and such other non-voting liaison representatives that the Secretary deems are necessary for the Committee to effectively carry out its functions.

Due to the diversity of its membership, 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 may not follow their advice due to other overriding concerns. Thus, while some of the actions recommended by CLIAC may eventually result in changes to the regulations, the reader should not infer that all of the Committee's recommendations will be automatically accepted and acted upon by the Secretary.

III. CALL TO ORDER – INTRODUCTIONS/FINANCIAL DISCLOSURES

Dr. Thomas Hearn, Designated Federal Official (DFO), Clinical Laboratory Improvement Advisory Committee (CLIAC), and Deputy Director, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), CDC, welcomed the Committee and the members of the public, acknowledging the importance of public participation in the advisory process. He introduced the newly appointed DFO, Dr. May Chu, Director, Laboratory Science Policy and Practice Program Office (LSPPPO), who would be taking over for him as of the end of this meeting.

Ms. Elissa Passiment, Chair, CLIAC, welcomed the Committee and called the meeting to order. All members then made self-introductions and financial disclosure statements relevant to the meeting topics.

IV. AGENCY UPDATES AND COMMITTEE DISCUSSION

Centers for Disease Control and Prevention (CDC) Update

Addendum A

Devery Howerton, Ph.D.
Director, Division of Laboratory Science and Standards (DLSS)
Laboratory Science, Policy and Practice Program Office (LSPPPO)
Office of Surveillance, Epidemiology and Laboratory Services (OSELS)
Centers for Disease Control and Prevention

Dr. Howerton's presentation highlighted the major activities underway within the DLSS. She related recent organizational changes and provided an update on the status of the proposed rule for proficiency testing (PT) which was discussed at the September 2010 CLIAC meeting. She then reviewed the status of two cytology cooperative agreements funded through 2011. The College of American Pathologists (CAP) has conducted a survey of all national cytology laboratories to assess current testing practices in an effort to determine recommended practices. The survey findings will be posted on the CAP website (www.cap.org) and a consensus conference is planned by CAP for June 2011. The Michigan Public Health Institute (MPHI) has conducted a survey of physicians that includes questions about a variety of clinical issues related to cytology test ordering and interpretation of results. Results of this survey may also lead to guideline development and publications. Dr. Howerton discussed the status of the development of products to promote good laboratory practices for waived testing and molecular genetic testing (MGT). For waived testing, educational posters and booklets are now available and an on-line tutorial is under development based on recommendations previously published as a Morbidity and Mortality Weekly Report: Recommendations and Reports (MMWR R&R). Also, based on MMWR recommendations for MGT, fact sheets for health professionals and consumers are now available, with an on-line tutorial in the development phase. Dr. Howerton concluded by announcing that the publication of an MMWR R&R focused on good laboratory practices for biochemical genetic testing and newborn screening is targeted for November 2011 and she described the overall intent and expected outcomes of this document.

Committee Discussion

- Several members voiced their appreciation for the new educational materials. A member inquired about the possibility of providing similar information for patients being tested. Another member suggested the definitions of over-the-counter testing and waived testing be clarified for physicians in educational materials pertaining to waived testing.

- A member asked if the proposed federal budget cuts would affect the CLIA activities at CDC. Dr. Howerton noted the CLIA program is not operated with appropriated funds but rather through user fees and would, therefore, not be directly impacted.

Board of Scientific Counselors (BSC) Update

Addendum B

Ms. Elissa Passiment, Chair, CLIAC
Executive Vice President
American Society for Clinical Laboratory Science

Ms. Passiment reported on a meeting of the Office of Infectious Diseases (OID) Board of Scientific Counselors that she attended in December 2010. The goal of the meeting was to provide updates and discuss a draft of CDC's Infectious Disease Framework, whose purpose is to provide overarching priorities to sustain and improve disease prevention and control efforts. The discussion centered on the gaps identified during a series of challenging situations which included the influenza H1N1 outbreak, cholera epidemic in Haiti, and global vaccination efforts. Ms. Passiment indicated the framework will ultimately serve as a guidance document for CDC's infectious disease efforts and as a roadmap for collective action among CDC's public health partners. She shared workgroup feedback gathered on the framework, including the recommendation that "revitalizing" the public health infrastructure is terminology that should be avoided; however, efforts to ensure strong, capable, and forward-looking public health capacities (e.g., use of new technologies, electronic laboratory reporting, novel surveillance and communication strategies) remain critical.

Committee Discussion

- A member commented that state laboratories are considered leaders for limited confirmatory testing for infectious diseases but are suffering from workforce shortages and loss of funding in the current economic crisis. Another member agreed and pointed out that as state laboratory capacities diminish, testing is being passed on to federal partners.
- Dr. Hearn expressed appreciation for Ms. Passiment's contributions in representing CLIAC and in bringing the perspective of clinical and commercial laboratories to the BSC's discussions.

Food and Drug Administration (FDA) Update

Addendum C

Alberto Gutierrez, Ph.D.
Director, Office of In-Vitro Diagnostic Device Evaluation and Safety (OIVD)
Center for Devices and Radiological Health (CDRH)
Food and Drug Administration

Dr. Gutierrez began his presentation with a brief update on the organizational changes at the FDA. He reported on the 2011 agency priorities to implement a total product life

cycle approach, enhance communication and transparency, strengthen the FDA workforce and workplace, and proactively facilitate innovation and address unmet public health needs. Following this, he addressed the CDRH plan of action for the implementation of 510(k) and science recommendations to foster medical device innovation and improve oversight of these devices. Regarding whole genome sequencing he said the FDA has been trying to determine the best way to regulate the new sequencers that have appeared on the market. The FDA is facing different regulatory issues with the new technology and has convened public meetings with manufacturers in order to find ways address these issues. Dr. Gutierrez discussed agency efforts to assess the status of direct to consumer (DTC) genetic testing and laboratory developed tests (LDTs). He reviewed recently published FDA guidances on a variety of detection methods for microbial agents and mentioned significant recalls including Abbott glucose strips. He concluded his presentation by announcing that negotiations have begun concerning the medical device user fee program.

Committee Discussion

- One member asked if the guidance for LDTs would overlap with the National Institute of Health's genetic test registry. Dr. Gutierrez responded that while the FDA is looking for positive synergy with this registry, FDA guidance will address all LDTs and not just genetic tests.
- A member asked for an explanation of how medical device fees are different from the medical device tax found in the Healthcare Reform Act and if an opportunity for negotiation exists. Dr. Gutierrez said that implementation of the medical device tax is two to three years in the future and that Congress is aware of currently required medical device fees.
- A member urged the FDA to utilize subject matter experts in convened committees. Dr. Gutierrez responded that FDA uses committees when reviewing certain devices and also uses outside workshops and public meetings to obtain broad input as part of their reviews.
- A member asked whether there is active harmonization within FDA when there is a drug/device combination in co-development. Dr. Gutierrez acknowledged this is challenging for both FDA and industry. He stated the two FDA centers have worked to address this issue and have made improvements to better coordinate their reviews.
- A member asked what could be done about the off-label use of tests such as the HbA1c point-of-care test which is being used off-label as a diagnostic indicator for diabetes. Dr. Gutierrez stated that FDA is aware of the HbA1c issue. Letters have been sent to manufacturers that the cleared devices, some of them waived, were not intended to be used for the diagnosis of diabetes. The FDA reviews devices based on manufacturers' claims, and the letters instructed manufacturers that if they wished to include diagnosis of diabetes as one of the intended uses of the HgbA1c devices, they needed to have this claim reviewed by the FDA. He also stated the FDA monitors claims and complaints with subsequent follow up.

Jonathan Jarow, MD
Medical Officer
Division of Reproductive and Urologic Products
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration

Dr. Jarow addressed the issue of prostate specific antigen (PSA) testing providing false reassurances for men taking 5 α -reductase inhibitors thereby leading to a delay in the diagnosis of cancer. He asked for CLIAC's input on how to make laboratories that perform PSA testing and physicians who use test results for patient diagnosis and treatment aware of this potential issue. He provided an overview of prostate cancer statistics, the properties of PSA, and explained how taking 5 α -reductase inhibitors can cause reduced PSA levels of approximately 50% within 3 months of their initial use. He described two clinical trials which demonstrated this acute reduction, with a chronic effect of stabilization or gradual decline. The doubling of the PSA value, which he added is done in some instances, is not valid for long term management. Therefore, PSA results must be interpreted with caution in men taking these inhibitors to avoid false reassurance because any increase in PSA is of concern. He suggested that communication strategies include product labeling, outreach to professional groups, and adaptation of PSA laboratory reports to include proper interpretation of results when these drugs are being administered for accurate diagnosis and management of disease.

Committee Discussion

- The Chair commented that the doubling of PSA values is not common practice in clinical laboratories. Dr. Jarow indicated that the double blind placebo trials showed this is common practice among the healthcare providers who receive the test results.
- A member asked if the proposal is to conduct a study to determine different normal ranges for men who are on these medications versus those who are not. Dr. Jarow stated there is no normal range that can be indicated on a laboratory report for those on the medications. The proposal is to put verbiage on the laboratory report that says if the patient is taking one of these drugs the interpretation of the test has to be altered. The member proposed FDA develop text to be placed on the test report that all laboratories may uniformly use. Another member added this may not be possible with electronic result reporting and that clinical decision support may be useful.
- One member proposed utilizing proficiency testing (PT) programs as a mechanism for providing information to laboratories and placing the PSA test interpretation information in laboratory and hospital newsletters.
- The Chair summarized the discussion and noted that including information on every PSA test report would not resolve all of the challenges and suggested that FDA consult with pathologists and medical experts to identify solutions.

Harriet Walsh, M.A., MT (ASCP)
Deputy Director, Division of Laboratory Services
Center for Medicaid and State Operations
Centers for Medicare & Medicaid Services

Ms. Walsh began her presentation with an overview of CLIA statistics, which reflect an increase of approximately 7,000 laboratories, primarily those with Certificates of Waiver, and noted the CMS top 10 deficiencies showed relatively no change. She said CMS is continuing to meet yearly with the Partners in Laboratory Oversight to pursue the common goal of assuring quality laboratory testing. She commented CMS clarified their current regulatory guidance for test ordering, record retention, and result reporting when using electronic health records, and stated standards and practices for electronic exchange of laboratory information are still evolving. She noted the physician signature requirement on paper laboratory test requisitions under the CY2011 Physician Fee Schedule proposed rule will be withdrawn before the April 1st effective date. Ms. Walsh next gave an update on the status of the cytology PT proposed rule, stating approximately 6000 comments were received in response to publication of this rule in 2009. CMS has concluded many of the proposed changes to cytology PT can be addressed through guidance or administrative policy changes. In response to a CLIAC request for additional data on cytology PT failure rates, Ms. Walsh reported that CMS will continue to monitor those individuals that score less than 90%. While the percent of individuals in this category has remained at 3% for cytotechnologists and pathologists with cytotechnologists, the majority of these result from the “autofailure” (calling a high grade lesion normal). Ms. Walsh concluded her presentation by briefly touching on the growth of waived testing necessitating short and long term goals to improve oversight.

Committee Discussion

- A member asked for information on the perceived increase in diagnostic companies or research laboratories seeking CLIA certification. Ms. Walsh indicated this information may be located on the CLIA website (<http://www.cms.hhs.gov/clia/>).
- Another member emphasized the need for new data regarding cytology PT and urged CMS to gather and present additional data. Ms. Walsh stated CMS will continue to monitor cytology PT and will periodically provide updates.
- One member asked the reason for the decline in the number of accredited laboratories. Ms. Walsh stated CMS does not have any data that would explain this and there may be several reasons for the decrease in these numbers.
- A member asked if there was a plan to provide the MMWR R&R Good Laboratory Practices for Waived Testing Sites to the waived testing sites with their Certificates of Waiver. Ms. Walsh stated that attempts are being made to educate those who do the testing and that materials are shared with these sites.
- With regard to the cytology PT proposed rule, a member stressed that some pathologists and cytotechnologists do not agree with maintaining the current status of the regulations. The Chair acknowledged cytology PT and new information on cytology testing practices need to be on the agenda for future meetings.

V. PRESENTATIONS AND COMMITTEE DISCUSSION

Coordinating Council on the Clinical Laboratory Workforce (CCCLW) Report

Addendum F

Christine Bean, Ph.D.
Laboratory Director
Public Health Laboratories
Division of Public Health Services
New Hampshire Department of Health & Human Services

Dr. Bean began her presentation by providing the mission and constituency of the Coordinating Council on the Clinical Laboratory Workforce (CCCLW). She provided statistics on the projected increase in clinical laboratory technician positions and the shortage of graduates for these positions by 2016. Data were provided showing a decrease in the number of National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) programs and the low number of projected graduates from these programs, which will add to the shortage of clinical laboratory technologists. Dr. Bean then introduced the three CCCLW strategic action workgroups that are trying to address the workforce shortage issues. The first workgroup, Building the Business Case, is developing a strategy to focus on public awareness of laboratory professionals and the role of laboratory professionals in the patient care team. The Improving the Professional Profile workgroup is focused on promoting a positive image of laboratory professionals through the Labs and Lives segment of the Labs are Vital™ website (www.labsarevital.com). This workgroup also conducted two surveys to gather information on enhanced roles explored in Medical Technologist or Medical Laboratory Scientist programs. The findings from the surveys show that enhanced roles for these professions are minimal and educational programs have little opportunity to explore them. The third workgroup, Recruitment and Retention, is active in the creation of the Lab Science Careers website (www.labsciencecareers.com).

Committee Discussion

- One member agreed that increased recruitment of people into laboratory science professions needs to occur and added the message should extend to those who have not yet made career decisions, such as high school students. The Chair clarified that LabScienceCareers.com is designed for people looking into the field as a possible career path. This website will be linked to the Labs are Vital™ website at some point. Another member commented on a small state funded program in California, LabAspire, which is mainly targeted toward the public health laboratory workforce but also performs outreach to high schools and colleges about laboratory science.
- A Committee member commented on the gap between the projected graduates needed to fill laboratory science positions and the actual number of graduates from NAACLS programs. The member questioned if the difference in numbers results from a need to encourage students towards a career in medical laboratory science or from a shortage

of programs to accommodate the interested individuals. The Chair explained that in the late 1990's and early 2000's there were not enough people entering into medical laboratory professions. As a result of this as well as decreases in reimbursements and loss of faculty due to retirements, many hospital-based programs closed. However, with the current economy, careers in healthcare are becoming more attractive, including careers in medical laboratory science. With this revitalization of interest, there are now not enough educational programs available to accommodate people interested in laboratory science professions. CCCLW is working to expand or save the NAACLS programs.

- A member inquired if the CCCLW has been involved with healthcare reform and how it will affect the number of allied healthcare positions needed to cover the expected increase in testing. The Chair acknowledged that CCCLW has not ventured into the policy implications of the healthcare reform bill. CCCLW has invited a representative from the Health Resources and Services Administration (HRSA) to their next meeting in order to provide an introduction to their mission.
- One member suggested CCCLW work more closely with pathologists on the expanded role of medical laboratory scientists and encourage their inclusion in clinical consultations.

Introduction - National Institutes of Health (NIH) Genetic Testing Registry

Addendum G

Barbara Zehnbauer, Ph.D.
Laboratory Research and Evaluation Branch
Division of Laboratory Science and Standards
Laboratory Science, Policy and Practice Program Office
Office of Surveillance, Epidemiology and Laboratory Services
Centers for Disease Control and Prevention

Dr. Zehnbauer described the formation, goal, scope, and caveats of the NIH genetic testing registry (GTR). The registry is intended to provide a centralized online information resource for genetic tests by providing transparency on test availability and utility, locations of laboratories and test offerings, and data sharing for research and discoveries. Dr. Zehnbauer explained that the NIH conducts and supports basic, clinical, and translational medical research and includes a large number of public databases. The GTR will include any genetic test and will seek detailed information on molecular testing quality measures, provide more assay-specific performance characteristics, and will make this information available to users of the GTR. She explained that there are caveats related to the registry, those being that there is a lack of standards for common data elements, submitters of data are responsible for the content and quality of data provided, NIH does not verify the submitter's claim about test performance, and information may be misinterpreted or misapplied leading to adverse health decisions and public health risks. Dr. Zehnbauer concluded her presentation by asking CLIAC if they wished to make a recommendation to the Health and Human Services (HHS) Secretary regarding the NIH GTR.

Genetic Testing Registry

Addendum H

Cathy Fomous, Ph.D.
Senior Health Science Policy Analyst
Office of Biotechnology Activities
National Institutes of Health

Dr. Fomous began her presentation with the reasons for the development of a GTR, a single public source of comprehensive information about genetic tests. The Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) recommended that HHS establish a test registry to increase the transparency of genetic testing. The desired outcome of the registry would result in oversight improvement and better informed decisionmaking regarding genetic testing. She then reviewed the FDA activities and public meetings related to genetic testing which led to NIH's decision to develop the voluntary GTR. Dr. Fomous described the steps involved in the GTR development including meeting with CDC, Agency for Healthcare Research and Quality (AHRQ), CMS, and FDA for input on the request for information (RFI). Dr. Fomous provided the GTR RFI questions and an overview of the responses and concerns. She reviewed the focus questions and comments from the public stakeholders meeting held on November 2, 2010. The general agreement from the stakeholders was for NIH to use a phased approach when building the GTR. The initial phase will include single-gene tests for Mendelian disorders, pharmacogenomic tests, and test panels. The initial target audience is intended to be health care providers. Dr. Fomous ended her presentation with a review of the next steps including continued engagement with external partners and stakeholders in anticipation of a fall 2011 GTR launch.

The Association for Molecular Pathology (AMP) Response to NIH GTR RFI – Survey of Clinical Molecular Laboratories

Addendum I

Vicky Pratt, Ph.D., FACMG
AMP Professional Relations Committee
Chief Director, Molecular Genetics
Quest Diagnostics Nichols Institute

Dr. Pratt provided results on the AMP responses to the NIH GTR RFI. There were 63 respondents of which 93% worked in a clinical laboratory. Inherited disorders, somatic disorders, pharmacogenetics, biochemical genetics, and infectious diseases were the tests that a majority of respondents believed should be included in the GTR. The AMP respondents ranked health care providers as the most relevant audience, which is the initial target audience of the NIH. Dr. Pratt showed the top data elements that respondents would be willing to provide to the GTR. These included elements similar to AMP's own current test registry which contains a directory of laboratories that provide molecular testing for infectious diseases, solid tumors, and hematopathology. There was a low interest in providing performance characteristics and confidential or proprietary

information. The major concerns from respondents were the increased burden for laboratories to maintain up-to-date information in the registry; how the information would be used by competitors, payers, and regulators; accuracy of data due to lack of curation; disclosure of propriety information; the extent of NIH involvement in clinical activities; how GeneTests will be affected; and how the GTR will relate to the FDA with the potential FDA oversight of laboratory developed tests. Dr. Pratt concluded by providing AMP's response to questions addressed at the public stakeholders meeting.

Committee Discussion

- A member wished to know what safeguards could be put in place to prevent the users of the NIH GTR from misunderstanding, misinterpreting, or misusing the information. Another member commented on the difficulties in delineating basic information such as what tests are considered genetic and which laboratories are performing those tests.
- One member asked if the NIH will be editing the data for congruency, thereby assisting healthcare professionals with its interpretation. Dr. Fomous responded that the data will not be edited. Several members expressed concern about the validity of the data due to the lack of editing.
- The Chair suggested that there would need to be some mandatory basic information provided for any test submitted in order to compare tests. Dr. Fomous responded that there will be a subset of required fields or minimal information the submitters will be required to provide, but those fields have not been determined. Some data fields may have pull down menu options but other fields will be open text entry, input by the laboratory. She stated that the NIH GTR is voluntary and laboratories do not have to provide information for every data field. Since the NIH GTR is still in development, comments and input on any aspect of the registry will be noted.
- One member commented that many laboratories participate in GeneTests, a publicly funded medical genetics information resource developed for physicians, other healthcare providers, and researchers; available at no cost to all interested persons. The GeneTests database and website are hosted at the National Center for Biotechnology Information (NCBI) and contains some of the same information as described for the NIH GTR. The member stated that GeneTests is an easily accessible resource; although voluntary, laboratories tend to participate to advertise their testing menus.
- A Committee member suggested moving all the data from GeneTests into the NIH GTR then allowing laboratories to fill in the missing data elements. Dr. Fomous concurred that was the intent of the NIH GTR. There would be a period of overlap before GeneTests is phased out. The Chair commented that rather than overlapping the two registries, structuring a link from GeneTests to the GTR would promote data entry into the GTR from the start. Dr. Fomous remarked there is a plan to link the NIH GTR to GeneTests, but recognized that there are some laboratories that will continue to use GeneTests as a fallback if they cannot find the information needed in the NIH GTR, so for a period of time both registries will exist. A member suggested that the total cost of care and the use of these tests for the patient's outcomes is a critical component to include in any database. Another member added healthcare

plans are struggling to determine who should be paying for these tests as well as how the information will be used. A member pointed out that the variations in Current Procedural Terminology (CPT) code reimbursements across the country may influence the cost of testing. Providing laboratory costs for tests in a database could result in shopping for the lowest price.

- Several members suggested the NIH use the format of GeneTests as a pilot or a model for the GTR to avoid potential confusion caused by having two similar databases. Since the GeneTests website is familiar, transparent, and the database already contains information, it would just need to be expanded to allow inclusion of the broader range of tests and additional data elements proposed by the NIH GTR. Dr. Fomous answered that the NIH plans to include additional tests, such as pharmacogenomic tests, and information beyond what is currently available in GeneTests, in the GTR. Another member requested a reiteration of the differences between the GTR and GeneTests. The top third of elements that the AMP respondents would be willing to provide to the GTR are currently in the GeneTests database and updated on an annual basis. The Chair asked since the GeneTests database is part of the NCBI, a government funded group, why couldn't GeneTests be used as a model for phase one and then additional elements could be added in phase two. Another member agreed and added the information should be mandatory. Dr. Zehnbauer responded NIH has been asked that question and their response is they feel it would be easier to create a new database than to try to amend the GeneTests' database structure. The proposal would be to take all the data in GeneTests and move it into the NIH GTR. Dr. Fomous agreed, elaborating that there is an infrastructure problem with GeneTests and it is easier to start over with the NIH GTR. The NIH GTR is intended to only replace the searchable laboratory directory component of GeneTests; *GeneReviews* will remain as the directory.
- The Chair asked why AMP's respondents felt it would be difficult to provide specificity, sensitivity, and predictive values. Dr. Pratt responded laboratories document analytical sensitivity and specificity, but often do not have the patient pools available to document clinical sensitivity and the clinical specificity of a particular test. Also, currently many laboratories voluntarily provide that information to GeneTests and it is summarized in *GeneReviews* for specific tests, so it seemed overly burdensome for individuals to provide clinical validity data again to the NIH GTR. Another member commented that in the NIH GTR, the source of clinical validity data for a test could be literature data or the laboratory's own data and each could be interpreted differently, leading to confusion.
- Dr. Gutierrez asked if clinicians will have adequate information to make decisions related to testing if laboratories are reluctant to provide performance characteristics to the NIH GTR. Dr. Pratt clarified that laboratories have this data and are willing to provide it directly to physicians and patients, but find it burdensome to maintain in a central database.
- One member suggested that if the target audience is healthcare providers, the information in the NIH GTR needs to focus on assisting those providers in making informed decisions about genetic testing. Another member agreed adding the registry needs to be prescriptive in addressing the issues encountered by physicians concerning genetic testing. The Chair asked if the NIH has received any input from

healthcare providers as to what is needed to make informed decisions about genetic tests. Dr. Fomous answered a better understanding of test limitations, patient populations for which the test is intended, and whether or not the test is FDA approved are specific aspects that healthcare providers have requested.

- A member expressed concern about the overall direction that genetic testing seems to be taking in treating it as a unique subset of laboratory testing different from other laboratory testing. Would routine tests, such as hemoglobin electrophoresis for hemoglobinopathies, be considered genetic tests that would need to be added to a registry? The Chair emphasized that genetic tests are covered under CLIA and asked why they are being singled out as opposed to any other laboratory tests. Dr. Fomous answered that SACGHS did not believe in genetic exceptionalism and many of the recommendations in their oversight report cover all laboratory tests. The recommendation was for a registry to cover all laboratory tests, but due to the fact that much of the information is unknown, genetic tests seemed to be a good starting point.
- Another member added that SACGHS originally suggested utilizing CMS's Online Survey, Certification, and Reporting (OSCAR) database to determine if laboratories were CLIA certified and performing testing. The member said several public comments to the SACGHS document suggested combining the GeneTests registry and the OSCAR database in order to cover all laboratory testing. Ms. Walsh explained that the OSCAR database has laboratories listed by their CLIA number, and includes some specific information such as laboratory director, specialties, and last survey dates. However, some elements such as the laboratory's test menu are not in the database. Another member clarified that SACGHS knew the limitations of the OSCAR database and the recommendation was to expand it to include the specific elements that were used for genetic tests in GeneTests. Dr. Zehnbauer reminded the Committee that accreditation organizations have the testing menu for all laboratories that they accredit, but that information is not entered into the OSCAR database. The burden of entering that information into a registry is then shifted to the laboratories.
- One member commented that the utilization of biomarker detection as a diagnostic test to identify which type of chemotherapy regimen a cancer patient should follow seems to be a complicated issue compared to simply testing for one gene and may require a more advanced format than GeneTests provides. Another member noted that when a laboratory is performing a twenty biomarker screen, each of those biomarkers would have a separate entry in that laboratory's testing menu in GeneTests. If there was a test that was considered a standard panel of tests, then the panel would also be entered into GeneTests.
- A member noted the Committee seems to agree with the strategy of a registry but there are concerns about the logistics of the registry. The member requested more information on the logistics of the registries before any formal recommendation is made by CLIA. Dr. Fomous offered to provide more information about the data elements, the format of data elements, and whether the entry of certain elements would be required or voluntary and gave the link to the website where the information could be found www.ncbi.nlm.nih.gov/gtr/. The Chair asked if the registry would be able to delineate if a laboratory is reporting any of the statistics from reference literature or reporting from their own data collection because this topic is a major

concern. Dr. Fomous responded that field definitions will be provided; some data fields will have a more standardized format while others will be text entry. She requested that anyone who is interested may beta test the NIH GTR and provide feedback on the definitions to determine if they are sufficient.

- In response to the question posed to CLIAC by Dr. Zehnbauer regarding the GTR, the Chair summarized that prior to making a recommendation to HHS the Committee needs more clarity on the vision for the NIH GTR; what data elements to include in the database, how the data will be verifiable and usable, and more information on the logistics of the registry.

Advances in Clinical Cytogenetics

Addendum J

Barbara Zehnbauer, Ph.D., FACMG
Chief, Laboratory Research Evaluation Branch
Division of Laboratory Science and Standards
Laboratory Science, Policy and Practice Program Office
Office of Surveillance, Epidemiology, and Laboratory Services
Centers for Disease Control and Prevention

Dr. Zehnbauer provided an introduction to cytogenetic testing and described the advances in testing methodologies. Karyotyping was considered the state of the art method twenty years ago when the CLIA regulations were implemented. For a detection of a chromosome change by karyotyping, five million base pairs of DNA must change. At this resolution, karyotyping is useful for chromosome morphology, mapping, translocations, deletions, and insertions. Molecular cytogenetic methods such as fluorescent in situ hybridization (FISH) were introduced in the 1980s. This method increased resolution by an order of magnitude from 5 million to 500,000 base pairs. FISH can detect changes in chromosomal segments in both interphase nuclei and chromosome metaphase analysis. Changes in chromosome number, chromosome morphology, and DNA rearrangements are detectable by FISH methods. More recently, cytogenomics methods have increased resolution to the 50,000 base pair level. Cytogenomic methods can detect copy number variations (CNVs) of gains or losses of DNA on each chromosome but do not detect inversions or translocations. These methods include comparative genomic hybridization arrays or chromosomal microarrays, and single nucleotide polymorphism arrays. Dr. Zehnbauer discussed the challenges involved with performing cytogenomic methods including the combined technologies of molecular and chromosome genetics, large amounts of quantitative data to visualize across the human genome and consider during interpretations, plus the uncertain clinical utility of the information in many instances. Finally, she presented CLIAC with three questions for consideration in light of these advances in technology.

Chromosomal Microarrays

Addendum K

Shashikant Kulkarni, Ph.D., FACMG

Director, Cytogenomics and Molecular Pathology
Associate Professor, Pathology and Immunology
Associate Professor, Pediatrics and Genetics
Washington University Physicians
Washington University School of Medicine in St. Louis

Dr. Kulkarni presented an overview of chromosomal microarray (CMA) usage as a cytogenomic diagnostic tool. He illustrated comparative genomic hybridization arrays and single nucleotide polymorphism (SNP) arrays and highlighted the differences among bacterial artificial chromosome arrays, oligonucleotide arrays and SNP whole genome arrays. Each technology has the capacity to identify CNVs of sequences throughout the human genome but with increasing degrees of resolution. Interpretation of the clinical significance of CMA results is due to the many CNVs which have been described in both disease and normal states; 5-25% of the human reference genome is comprised of CNV regions. The preferred term used for designated pathogenic CNV is copy number alteration (CNA). Dr. Kulkarni described the four major criteria for assigning likelihood of pathogenicity CNA results. The pathogenic and benign criteria have supporting data in the published literature information, but variants of uncertain significance and variants of likely pathologic significance are not as well documented for clinical significance. The increase in detection rates of CNAs with array testing was illustrated and a simplified algorithm for clinical chromosomal microarray testing was provided. In conclusion, Dr. Kulkarni addressed the gaps in standards for CMA testing and provided information on current activities to address those gaps.

Genetic Testing Reference Material Program (GeT-RM)

Addendum L

Lisa Kalman, Ph.D.
Health Scientist
Laboratory Research Evaluation Branch
Division of Laboratory Science and Standards
Laboratory Science, Policy and Practice Program Office
Office of Surveillance, Epidemiology, and Laboratory Services
Centers for Disease Control and Prevention

Dr. Kalman began with an overview on the usage of reference materials and emphasized the lack of publicly available reference materials for genetic testing. She demonstrated the growth in the number of genetic testing laboratories and number of genetic tests offered. The reference materials that are available for a very few genetic tests often do not include all variants tested in clinical assays. Dr. Kalman introduced the GeT-RM program, a collaborative CDC-based program to improve the availability of reference materials for genetic testing. She reviewed the roles, process, website, and progress of the GeT-RM which has characterized over 200 genetic testing reference materials. These materials are available from the National Institute of General Medical Sciences repository at the Coriell Cell Repositories. Dr. Kalman explained the expressed need for reference materials for cytogenetic microarray testing and discussed a new GeT-RM project to

create two reference material panels for cytogenetic microarray testing; a clinical panel representing common cytogenetic abnormalities and a probe validation panel to evaluate the ability of each array probe to detect duplications or deletions. Dr. Kalman also presented an overview of the partners that are working on this project and concluded her presentation with the progress to date.

Committee Discussion

- A member inquired if there were any plans to provide reference materials for infectious disease genetic testing. Dr. Kalman responded that she has performed surveys through AMP, but has been unable to determine what reference materials are most needed by the infectious disease testing laboratories.
- One member agreed that proficiency testing using known genetic cell lines would help the laboratory achieve the correct test results. However, currently, the results of genetic tests are reviewed by a certified genetics specialist and the director of the laboratory, therefore, the ability of a laboratory to interpret results is dependent on the quality of the director.
- Dr. Kulkarni explained the College of American Pathologists (CAP) has been introducing educational proficiency testing over the last two years. Another member added that it is a mechanism for alternative assessment provided twice a year.
- A member commented there are standards for cytogenetic testing set by the American College of Medical Genetics (ACMG) and emphasized that laboratories performing microarray testing are inspected just like other cytogenetics laboratories.
- A member explained that CNVs are not exclusive to cytogenomics, they exist in molecular genetics as well. Variants exist within everyone's genome. The technology is different, but some of the problems are the same. Dr. Kulkarni agreed and stated there are projects ongoing in which additional information about variants will be elucidated.
- In response to the question proposed, "*Do clinical cytogenetic regulations adequately assess cytogenomic laboratory practices?*," the Chair summarized that chromosomal microarray testing is an evolving technology and the GeT-RM project is a huge step forward in assisting laboratories meet some of the quality assurance issues. At this time, CLIAC does not see a gap in the CLIA regulations that needs to be addressed.

Clinical Laboratory Integration into Healthcare Collaborative (CLIHC)TM

Addendum M

Julie Taylor, Ph.D.
Senior Health Scientist
Division of Laboratory Science and Standards
Laboratory Science, Policy and Practice Program Office
Office of Surveillance, Epidemiology and Laboratory Services
Centers for Disease Control and Prevention

Dr. Julie Taylor gave a brief introduction of the Clinical Laboratory Integration into

Healthcare Collaborative (CLIHC™). She reviewed the history of the project including past related institutes that served to identify “gaps” and important opportunities for improving laboratory quality. Dr. Taylor said the Integration Workgroup was initiated in 2008 to address opportunities that had been identified in the 2007 Managing for Better Health Institute. One of these was that of improving the selection of laboratory services and the interpretation of test results by institutionalizing new practice models. The Workgroup was also tasked with promoting the development of programs and training or education courses that link clinicians, clinical and public health laboratory providers, and patients in healthcare. Dr. Taylor explained the Workgroup members sponsor projects and, as needed, engage additional assistance to accomplish goals. She concluded by saying the Integration Workgroup, which was renamed to CLIHC™ in 2010, is led by Dr. John Hickner, representing clinicians, and Dr. Mike Laposata, representing the laboratory. Altarum, the contractor, assists with the general administration of CLIHC™ and the surveys it is conducting.

Clinical Laboratory Integration into Healthcare Collaborative (CLIHC) – An
Update on Activities *Addendum N*

Mike Laposata, M.D., Ph.D.
Executive Vice Chair of Pathology
Pathologist-in-Chief, Vanderbilt University Hospital
Director, Division of Laboratory Medicine and Clinical Laboratories
Vanderbilt University

Dr. Laposata began the update to the CLIHC’s™ activities by explaining two major unmet needs of clinicians with respect to clinical laboratory services: appropriate laboratory test selection and appropriate interpretation of test results. He discussed a literature review demonstrating the last decade’s rapid rise in the detection of errors with these processes and the associated adverse effects. Based on recommendations from the CDC institutes, CLIHC’s™ overall plan focuses on measures to improve quality in these two areas. The plan includes: identifying the major issues associated with appropriate test selection and result interpretation; creating teams of expert laboratorians and clinicians to collect relevant data to illustrate problems and possible solutions; and publishing the information in peer reviewed manuscripts. Dr. Laposata continued by discussing CLIHC’s™ current six projects, describing the issues, goals, and recognizing the experts working on each project. Dr. Laposata concluded his presentation with a discussion of how increases in testing have changed the role of the laboratory in the past several decades and how the role of clinical laboratory directors has not kept pace. He credited the success of CLIHC™ on its unique composition which provides for both laboratorian and clinician perspectives. He also emphasized the benefits of CDC as a sponsor as opposed to a professional organization’s own agenda driving the workgroup’s initiatives.

Committee Discussion

The Chair thanked Dr. Laposata for his presentation and asked the Committee to consider four questions pertaining to CLIHC™ during their discussion.

- One Committee member asked whether CLIHC™ had considered collaborating with radiology to produce diagnostic algorithms. Dr. Laposata said the workgroup had not yet progressed that far. However, Vanderbilt University Hospital has put together a group, the Diagnostic Management Team that brings multiple laboratories together in an effort to coordinate patient care and has plans to include a radiologist as part of the team within the next year. He said they are also considering forming a Department of Diagnostics to include radiology, anatomic and clinical pathology. The Committee member commented that Dr. Laposata seemed to be building a team that could assist family or internal medicine and asked how they intended to engage specialists who may be resistant to this type of assistance. Dr. Laposata replied the key is to include the specialist as the team is built.
- A Committee member brought up the issue of how a more complete analysis is needed that considers all test results in context of the total patient profile as opposed to simply labeling results as critical or not critical and only reporting those results that reach the critical value threshold. Dr. Laposata replied that, although this is not a CLIHC™ project, he has been working on the issue and acknowledged its complexity. He said the solution will likely require an information technology (IT) solution as well as engagement from other clinical partners.
- A member acknowledged selecting the appropriate laboratory test is challenging to primary care physicians who would like to be able to pick the correct test and would welcome meaningful consultation to that end. Healthcare reform, as an integrated delivery system, should support reimbursement of laboratory consultation. Another member added that test menu abbreviations and definitions of abbreviations were important and that an IT solution is necessary.
- One member said that laboratory consultation is taught to the clinical pathologists at their medical center and invited CLIHC™ to have dialogue with them. Dr. Laposata said that would be helpful as the project on the lack of training on clinical consultation moved forward. Dr. Taylor agreed and asked for anyone that had good models to contact her.
- The consumer member commented that responsibilities placed on hospitalists to care for every kind of disease is frightening. Another member mentioned that hospital patient advocates should also be educated about these issues to raise awareness. Dr. Laposata welcomed public awareness about physicians not being taught about diagnostic testing, especially the lack of training in clinical pathology to those who could provide consultation. One cause, he said, of this lack of consultation is the absence of payment for clinical pathology consultative ability as opposed to payment for consultation in anatomical pathology.
- A member said that integration of point-of-care testing into clinical practice was causing issues related to overconfidence in results from these tests and that this should also be considered by the CLIHC™ group. The member also related that in their laboratory, client call centers had been instituted to relieve the laboratory scientists from interruptions or from the burden of placing critical results calls or having to contact physicians for more information. However, the client call centers

have become a barrier between the laboratory scientists and physicians because the individuals who staff the call centers do not have the appropriate expertise to offer clinical consultation.

- A member encouraged providing incentives for existing pathologists to improve their skills in consultation.
- Dr. Laposata stated that the College of American Pathologists (CAP) has a strategy team looking at new opportunities for clinical pathologists that are resulting from the development of new technology. Dr. Taylor commented that CLIHC™ has been meeting with the CAP Transformation Team on this subject. One member added that CAP realizes that there is an overall change in medicine occurring and is facilitating the integration of pathologists more directly into patient care.
- A member asked if CLIHC™ was considering the issue of computer order entry test sets and the involvement of the clinical laboratory in developing these. Dr. Taylor replied that CLIHC™ is looking at how the process can be improved.
- One Committee member recommended integrating tools, such as the testing algorithms, into applications for portable electronic devices like smart phones or tablet computers. Another useful application would be an electronic system that combines laboratory results with pharmacy information and patient history and provides an alert to the physician if the combination yields a critical result.
- Another member recounted experience with physicians voicing a need for real time and succinct diagnostic support systems. The physicians' key request was a way to standardize naming of laboratory tests on a national basis. The member also mentioned the importance of a partnership between the clinician and the laboratory with respect to electronic medical records and clinical decision support and described how her system is initiating “best practice alerts” as a helpful concept for physicians.
- A member discussed the need for metrics to measure the amount of harm prevented by interventions that aid test selection and interpretation and how this could facilitate the adoption of such interventions. The focus should be on preventable harm. Dr. Laposata replied that this was the main focus CLIHC's™ Improvements in Test Selection and Result Interpretation by Clinicians (ITSRI) project.

Laboratory Medicine Best Practices: Transparent Methods for Patient-Centered, Evidence-Based Quality Improvement *Addendum O*

Rob Christenson, Ph.D., DABCC, FACB
Professor of Pathology, Medical, and Research Technology,
University of Maryland School of Medicine

Diana Mass, M.A., MT (ASCP)
Director and Clinical Professor (Retired),
Clinical Laboratory Sciences Program, Arizona State University
President Associated Laboratory Consultants

Dr. Christenson and Ms. Mass cooperatively related ongoing efforts to implement the Laboratory Medicine Best Practices (LMBP) Initiative, sponsored by CDC. The focus of

this initiative is to evaluate effective quality improvement practices for critical activities in laboratory medicine. They noted that LMBP differs from the Agency for Healthcare Research and Quality's (AHRQ) Medical Test Reviews in that AHRQ's Medical Test Reviews consist of studying a single medical test while LMBP consists of systematic evidence reviews that rate the quality of evidence for laboratory medicine quality improvement practices. They discussed the need for the use of evidence-based laboratory medicine to ensure patient-centered outcomes. LMBP specifically rates evidence based on the "A-6 Cycle" which consists of six steps; ask, acquire, appraise, analyze, apply, and assess. The process includes the evaluation of data from published and unpublished quality improvement projects. A primary goal of the LMBP initiative is to disseminate information on the effectiveness of pre-and post-analytic laboratory medicine practices. Dr. Christenson and Ms. Mass presented an example of the A-6 process applied to practices to reduce blood culture contamination and also discussed activities aimed at educating laboratory professionals about quality improvement study designs. A series of online tutorials are expected to be posted on the LMBP website in the first quarter of 2011 to inform laboratory professionals about the process for gathering evidence and conducting an assessment. Dr. Christenson and Ms. Mass concluded their presentation with a description of key efforts to sustain the LMBP initiative. The presenters asked the Committee for their input and suggestions for sustainability. Information on the Laboratory Medicine Best Practices Initiative is available at www.futurelabmedicine.org.

Committee Discussion

- A Committee member asked about the development and subsequent dissemination of LMBP recommendations. Dr. Christenson responded dissemination of results from studies will include both articles in peer-reviewed journals and newsletters. Ms. Mass added that their findings are available on the LMBP website which will also be a tool for dissemination of information. She indicated that people can register on the website and e-mails will be sent to notify those who register when recommendations or new information is available. She then encouraged CLIAC members to register on the website.
- One member commented that there are a vast number of topics that could be studied by LMBP and suggested partnering with CLIHCTM as they have narrowed the topics down to five or six areas. Ms. Mass agreed that there was a need to partner with other organizations. Dr. Christenson replied that the two projects are different but there is some overlap between them.
- A member commented that the Emergency Care Research Institute, which publishes the "Emerging Technology Evidence Report," would be a natural partner for LMBP. Another member suggested that the FDA support the LMBP group as the information it gathers could assist in the FDA product reviews. Dr. Gutierrez responded that the FDA is primarily concerned with new products that have not been used in clinical laboratories so the literature for LMBP analysis would probably not exist but the FDA may request LMBP assistance with specific targeted topics.
- A member suggested LMBP partner with hospital lawyers because the final results from an evidence review may be superseded by the hospital's and physicians' concerns about preventing malpractice.

- A Committee member asked if the source of funds was taken into account when rating a study to be used in an analysis. Dr. Christenson replied that the sponsor of the study is disclosed.
- A member asked if authors were contacted when a publication appeared to be missing information needed for the review process. Dr. Christenson and Ms. Mass responded that authors were contacted and asked to provide missing data.
- A Committee member suggested hemolysis, cardiac biomarker testing, and a comparative study of point-of-care troponin testing versus laboratory testing be considered as additional topics to be studied.
- Dr. Guterrez suggested the use of glucose meters in hospitals as a topic, with the general suggestion to select topics that may have a large impact, even if there is not as much data available.
- Dr. Guterrez also stated that technological development may make many of the studies obsolete, therefore timing will be important. A member concurred and suggested that the team not expend its efforts reviewing the topic “rapid identification of bloodstream infections” at this time. Ms. Mass responded that is why the expert panelists are so important in helping to focus on what the questions should be. A Committee member suggested that expert panels should include manufacturers.
- The Chair suggested rewording the question about hemolysis found on the slide titled “Proposed new review topics.” Ms. Mass noted the comment and said that is a good example of how important it is to focus the question appropriately. Dr. Christenson noted that AHRQ and LMBP are posting their key questions on their websites for review and comment.
- A Committee member suggested publicly reporting when a topic does not yield enough information to allow analysis as this would be informative to practitioners. The Chair said that it might also serve as a call for more investigations on those topics.
- Ms. Mass commented that part of the LMBP educational strategy is to teach others how to construct a good quality study.
- One Committee member suggested that for important topics lacking evidence, money be made available and requests for proposals be made that specify what data are needed.
- A member commented that the program is valuable to the laboratory community and asked what the plans were for sustaining it. Another member remarked a possible plan for the program could involve graduate schools listing LMBP research as acceptable for a Master’s thesis. Ms. Mass agreed and stated that after a presentation given at the Clinical Laboratory Educators Conference, there was significant interest among educators to have students conduct this research. Dr. Christenson said that there was also interest among microbiologists.

VI. PUBLIC COMMENTS

**Cytology Education and Technology Consortium (CETC)
American Society for Clinical Pathology (ASCP)
Internet Letter**

***Addendum P
Addendum Q
Addendum R***

VII. ADJOURN

Ms. Passiment and the Committee acknowledged and thanked Dr. Hearn for his years of service to the CLIAC and wished him well in his future endeavors.

Ms. Passiment acknowledged the CDC staff that assembled the meeting agenda and provided meeting support, and thanked the CLIAC members and partner agencies for their support and participation.

Ms. Passiment announced the next CLIAC meeting would be August 31 - September 1, 2011 and adjourned the Committee meeting.

I certify this summary report of the March 2-3, 2011 meeting of the Clinical Laboratory Improvement Advisory Committee is an accurate and correct representation of the meeting.

Elissa Passiment, EdM, CLS(NCA), CLIAC Chair

Dated 5/03/2011