CLINICAL LABORATORY IMPROVEMENT ADVISORY COMMITTEE (CLIAC) RECOMMENDATIONS TABLE

DATE RECOMMENDED	CATEGORY	CLIAC RECOMMENDATION	STATUS
November 2-3, 2016	Biosafety	CLIAC proposes that the voluntary Laboratory-Associated Incident Reporting System (proposed by the CDC Blue Ribbon Panel recommendation in 2012) protect the privacy and confidentiality of reporting individual(s) and larger entities, e.g. via anonymity. The system should borrow from the principles of existing event-reporting systems and focus on incidents, near-misses, and mitigation measures that affect the safety of laboratory professionals. Finally, it should foster a non-punitive culture for reporting.	CLIAC sent a letter (dated November 29, 2016) to the Secretary, The U.S. Department of Health and Human Services (HHS), that included this recommendation. The letter can be found at http://ftp.cdc.gov/pub/CLIAC_meeting_presentations/pdf/Recommendations/Nov2016_HHSletter_BioSafety.pdf.
November 2-3, 2016	Autopsy	The CLIAC supports the IOM recommendation that Department of Health and Human Services (HHS) provide funding for a designated subset of health care systems to conduct routine postmortem examinations on appropriately defined categories of patient deaths (for example, those listed in the College of American Pathologists Guidelines for Non-Forensic Autopsies). These funds should be directly linked to proposals for data acquisition, including standardization of autopsy procedures and reporting (including death-certificates), with the expressed goal of understanding the value of autopsies for improving individual and health system outcomes.	CLIAC sent a letter (dated November 29, 2016) to the Secretary, The U.S. Department of Health and Human Services (HHS), that included this recommendation. The letter can be found at http://ftp.cdc.gov/pub/CLIAC_meeting_presentations/pdf/Recommendations/Nov2016_HHSletter_IOMRecommendation.pdf.

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November 2-3, 2016	Communication of Test Results	Recommendation 1a CMS should convene a multidisciplinary group* to – Generate a report describing a process for health care institutions to improve safe communication and follow-up of diagnostic test results to providers and/or patients with clear guidelines on timelines for communicating those results; and – Provide an implementation and evaluation plan for the process. Examples of guidance for the report include: – The 2015 VHA policy on communicating test results, http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=3148. – A similar project was the CDC's *Core Elements of Hospital Antibiotic Stewardship Programs*, http://www.cdc.gov/getsmart/healthcare/implementation/core-elements.html. *may include, but is not limited to, representatives from CMS, FDA, CDC, diagnostic industry representatives, relevant approved accrediting organizations, informaticians, human factors engineers, laboratory directors/professionals, clinician end-users, patient/consumer representatives, health IT developers/vendors, and other relevant professional organizations. Recommendation 1b CMS should recommend health care institutions create an interdisciplinary team comprised of clinical and diagnostic health care professionals, health IT, and other safety/human factors experts. This team should conduct periodic institutional self-assessments to address areas of risk and improvement related to safe communication and follow-up of diagnostic results. Examples of guidance include: – *Test Results Reporting & Follow-up* ONC SAFER Guide, https://www.healthit.gov/safer/guide/sg008. – Additional guidance could be obtained from the report in Recommendation 1a.	CLIAC sent a letter (dated November 29, 2016) to the Secretary, The U.S. Department of Health and Human Services (HHS), that included this recommendation. The letter can be found at http://ftp.cdc.gov/pub/CLIAC_meeting_presentations/pdf/Recommendations/Nov2016_HHSletter_IOMRecommendation.pdf.

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April 13-24, 2016	Laboratory Interoperability	CLIAC requests that the Office of the National Coordinator for Health Information Technology (ONC) Standards and Policy Committees each include a pathology informatician (pathologist with expertise in clinical informatics) as a committee member.	CLIAC sent a letter (dated May 9, 2016) to the Secretary, The U.S. Department of Health and Human Services (HHS), that included this recommendation. HHS response was sent on June 15, 2016. The letter and response can be found at http://ftp.cdc.gov/pub/CLIAC_meeting_presentations/pdf/Recommendations/Apr_2016_HHS_Interoperability.pdf.
April 13-14, 2016	Laboratory Interoperability	To facilitate wider uptake of standards for laboratory interoperability, HHS should endorse and stimulate adoption of an implementation guide/s for laboratory results reporting (e.g., The EHR-Lab Interoperability and Connectivity Specification (ELINCS) for orders available at: http://www.chcf.org/projects/2009/elincs); and successful pilots that arise from the S&I framework effort (http://wiki.siframework.org/Laboratory+Orders+Interface+Initiative)	CLIAC sent a letter (dated May 9, 2016) to the Secretary, HHS, that included this recommendation. HHS response was sent on June 15, 2016. The letter and response can be found at http://ftp.cdc.gov/pub/CLIAC_meeting_presentations/pdf/Recommendations/Apr_2016_HHS_Interoperability.pdf.

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April 13-14, 2016	Biosafety	CLIAC considers the matter of biosafety in clinical laboratories as an urgent unmet national need. We therefore recommend that CDC convene a multidisciplinary task force to develop a biosafety strategy for clinical laboratories that: - Includes stakeholders from all areas of clinical laboratories (including professional societies), diagnostic instrumentation industry, other relevant Federal agencies, and patient/clinician representatives. - Recommends areas requiring further research in clinical laboratory safety. - Develops tools, templates, and guidelines for risk assessment in all areas of the clinical laboratories, both for routine operations and for emerging infectious diseases. - Publishes interim materials and progress reports broadly, and specifically to CLIAC, to inform and to solicit input from the clinical laboratory and broader medical communities. - Describes cultural, regulatory, measurement, and evaluation strategies for goal achievement in biosafety. - Develops a framework for implementation of good clinical practices that also addresses transparent evaluation and monitoring of biosafety practices.	CDC is addressing this recommendation and updated CLIAC on November 2, 2016.
November 18-19, 2015	Procedural Changes	• CDC should review the process by which CLIAC creates, reviews, and edits official committee recommendations to allow a public forum for shared development and drafting of proposed recommendations prior to the meeting to facilitate more effective committee discussion.	CDC's Committee Management Office and General Counsel discussed the recommendation process at the April 13-14, 2016 CLIAC meeting.

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November 18-19, 2015	Prenatal Testing	• HHS and CDC should support the development of Non-invasive prenatal testing (NIPT)-related enduring educational materials accessible to patients and health care providers. In order to support effective patient care decisions, these materials should include simple language and visual graphics to effectively convey information about risks, benefits, and limitations of different types of prenatal testing. • HHS should require that ordering providers requesting non-invasive prenatal screening tests (of cell-free fetal DNA) should perform and document a pre-test discussion to inform the patient of risks, benefits, and limitations. • HHS should recommend labs performing NIPT to disclose information regarding test limitations and positive predictive values (likelihood that the fetus has a genetic condition) that is directly comparable to conventional techniques (e.g., by maternal age) while reporting results as well as risk interpretation and appropriate indications for confirmatory diagnostic testing.	CLIAC sent a letter (dated January 4, 2016) to the Secretary, HHS, that included this recommendation. HHS response was sent on March 7, 2016. CLIAC was provided the HHS letter and response on April 13, 2016. The letter and response can be found at http://ftp.cdc.gov/pub/CLIAC_meeting_presentations/pdf/Recommendations/Nov_2015_HHS_NIPT.pdf.
November 18-19, 2015	Electronic Health Records (EHR)	HHS should ensure the following next steps: • EHR content display related to laboratory data (including graphs) should be standardized such that all CLIA-required test report elements are on every laboratory display/graph. • National Institute of Standards and Technology (NIST) should create use cases for testing transmission and display of laboratory data in the pre- and post-implementation stages of EHR use in order to maintain semantic interoperability in various laboratory (clinical/anatomic pathology) settings. Use cases should start at the laboratory system and involve sending data across the interface for display in multiple EHRs. This would test the interoperability of comments, units, reference ranges, etc. (sometimes the reference ranges in the EHR are different than in the laboratory information system). • Consider the incorporation of CLIA use cases in next certification cycle. • The Centers for Medicare & Medicaid Services (CMS) should consider identifying activities considered as 'information blocking' and place multifaceted strategies to discourage such activities. For example, incentives could be built for offsetting the current high fees for laboratory/EHR interfaces.	CLIAC sent a letter (dated January 4, 2016) to the Secretary, HHS, that included this recommendation. HHS response was sent on March 7, 2016. CLIAC was provided the HHS letter and response on April 13, 2016. The letter and response can be found at http://ftp.cdc.gov/pub/CLIAC_meeting_presentations/pdf/Recommendations/Nov_2015_HHS_Interoperability.pdf.

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April 15-16, 2015	Safety	With regard to emerging infections, HHS should: 1. Provide oversight that ensures assessment of the safety and decontamination of laboratory instrumentation by manufacturers. 2. Ensure that biosafety training and assessment is required of all CLIA-certified laboratories, including personnel responsible for the preanalytical, analytical, and postanalytical phases of testing. 3. Ensure oversight, input, and resources into studies evaluating the safety of all laboratory practices, instrument testing, etc., so that studies are sound, robust, evidence-based, and applicable. 4. Develop a process for investigating and reporting laboratory acquired infections.	CLIAC sent a letter (dated May 6, 2015) to the Secretary, HHS, that included this recommendation. HHS response was sent to CLIAC on August 5, 2015. The letter and response can be found at http://ftp.cdc.gov/pub/CLIAC_meeting_presentations/pdf/Recommendations/Apr_2015_HSS_Biosafety.pdf.
April 15-16, 2015	EHR	HHS should convene a multidisciplinary stakeholder group that: • Includes, but is not limited to, representatives from ONC, CMS, FDA, CDC, industry representatives, health IT developers/vendors, all CLIA approved accrediting organizations, informaticians, lab directors/professionals, provider end-users, patient/consumer representatives, & other relevant professional organizations • Proposes a framework for achieving safe & effective lab interoperability (both system and patient facing) that encourages innovation and defines how to operationalize interoperability (and related deliverables) with detailed use cases • Provides both short term next steps and long term goals with definable measurable actions and outline who is responsible for these actions • Puts into place robust measurement and evaluation strategies for goal achievement.	CLIAC sent a letter (dated May 6, 2015) to the Secretary, HHS, that included this recommendation. HHS response was sent on July 24, 2015. CLIAC was provided the HHS letter and response on November 5, 2015. The letter and response can be found at http://ftp.cdc.gov/pub/CLIAC_meeting_presentations/pdf/Recommendations/Apr_2015_HHS_Interoperability.pdf.
November 5-6, 2014	Histocompatibility	CMS should explore: a. Regulatory changes or guidance(s) that would allow virtual crossmatching to replace physical crossmatching as a pre-requisite for organ transplant; b. Appropriate criteria and decision algorithms, based on the Virtual Crossmatch Workgroup input provided to CLIAC, under which virtual crossmatching would be an appropriate substitute for physical crossmatching. The determination of appropriate criteria and decision algorithms should involve a process that includes an open comment period.	CMS is investigating mechanism for implementation.

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November 5-6, 2014	Waived Testing	CMS should revisit the A19 request to open up the CLIA law to allow changes to the waived testing requirements and provide a description of the details of the A19 request at the next CLIAC meeting.	CMS reported on this during April 15-16, 2015 CLIAC meeting.
November 5-6, 2014	Waived Testing	HHS should facilitate the development of a non-punitive and non-regulatory self-assessment checklist-type tool and recommend it for biennial use by all Certificate of Waiver testing sites. It could also be used prior to or at the time a site first applies for a CLIA Certificate. • Items on the checklist should include recommended practices based on the "Ready? Set? Test!" booklet and should address known problem areas of importance (e.g., off-label use of waived tests). • The checklist could also assess whether the Certificate of Waiver site reports test system performance problems to the FDA. • Certificate of Waiver testing sites should be encouraged to keep copies of their completed assessments on file to be validated during CMS site visits and/or the assessments could be reported to CMS through an online portal.	Self-assessment checklist based on Ready? Set? Test! recommended practices was completed and is available at http://wwwn.cdc.gov/clia/Resources/WaivedTests/default.aspx.
August 21-22, 2013	Cytology	Clinical Laboratory Improvement Advisory Committee (CLIAC) endorses use of College of American Pathologists (CAP) Guidelines as a model for validation of whole slide imaging systems for clinical use.	No action required.

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August 29-30, 2012	EHR	CLIAC recognizes that serious patient safety risks can arise from errors in the order entry, transmission, display and interpretation of laboratory data in EHRs. Display and use of non-numerical laboratory information is an under-appreciated critical issue. Interoperability with LIS as well as correct transmission of data across multiple interfaces is also critical. The laboratory community can provide important input and solutions to these challenging problems. CLIAC makes the following recommendations: 1. Laboratory experts with experience in hospital, ambulatory or public health settings should be members of key ONC advisory committees and other agency groups that are setting standards and policies for laboratory information in EHRs. 2. Provider usability is an important strategy for mitigation of these patient safety risks. Further work in this area should be supported. 3. A national system for reporting EHR laboratory related safety events and near misses should be established to clearly define the prevalence, understand the underlying causes and stimulate the design of broad-based solutions. 4. A catalogue of various solutions for laboratory data should be created using work that has already been done and considering areas of expertise [e.g., human factors] that may not have been previously engaged.	CLIAC sent a letter (dated September 26, 2012) to the Secretary, HHS, that included this recommendation. HHS reported to CLIAC on steps being taken in response to the recommendation on August 22, 2013. The letter can be found at http://ftp.cdc.gov/pub/CLIAC_meeting_presentations/pdf/Recommendations/Aug_2012_HHS_EHR.pdf.
February 14, 2012	Cytology	1) CLIAC supports the use of data from operational studies, such as those presented to determine if the maximum workload limit using semi-automated screening instruments is appropriate. To discourage the use of maximum workload limits as productivity expectations, CLIAC recommends that standardized criteria be developed for use in determining workload limits for each individual performing screening. 2) Lowering the workload limits for screening Pap smears using a semi-automated device may result in improving the quality of testing. However, it could also lead to increased turnaround time and costs for obtaining test results and could have implications for access to testing.	CDC, CMS, and FDA developed a study plan with input from a cytology workgroup. In 2013 CDC funded a contract to collect workload data. Project completed in 2015 and data analysis is ongoing.

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August 31-September 1, 2011	Miscellaneous	Implement a work group to outline the scope of issues related to communication of laboratory testing information and propose approaches to address these issues for discussion by CLIAC.	The Communication in Informatics workgroup met July 11-12, 2012 and reported to CLIAC in August 29, 2012. Communication issues, in general, continue to be an ongoing topic of CLIAC discussions.
September 1-2, 2010	Cytology	CMS should analyze the cytology proficiency testing data directly in light of concerns expressed by the Committee on failure rates, reasons for failure, and trends and should present to CLIAC at the next meeting along with an analysis of the cytology NPRM and how it addresses these concerns.	At the March 2-3, 2011 CLIAC meeting, CMS presented their current data on failure trends from 2005-2010 and withdrew the proposed rule on April 8, 2011.

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September 1-2, 2010	Proficiency Testing	1. Analyte Inclusion/Prioritization and Grading Criteria a. There should be a defined list of analytes for which proficiency testing (PT) is required. If legally possible, those analytes should be separate from, but linked to, regulations, allowing the list to be more flexible. b. Inclusion Criteria for determining required PT analytes should be scientifically based. c. Factors to be considered for adding required PT analytes to subpart I of the CLIA regulations should include: i. Whether PT exists and material is available ii. The volume of testing for an analyte iii. Clinical relevance iv. Cost of adding an analyte d. Criteria used to assess clinical relevance of an analyte should include consideration of: i. Testing when a treatment decision is made solely on the result of that test. ii. Tests that have critical values associated, i.e. results that require immediate communication with clinicians due to their life-threatening nature or serious risk to the patient. iii. National practice guidelines that include testing the analyte. e. There should be a two-year phase in period for implementation of required PT after adding analytes to the list. f. The required number of PT challenges and frequency (five challenges, three times per year) should not be changed. g. Ideally every analyte should be assessed with traditional PT. If PT is not available, however, laboratories should continue to use alternative proficiency assessment as now required by CLIA.	Addressed in proposed PT rule in development.
September 1-2, 2010	Proficiency Testing	Criteria for Acceptable Performance – 2. Grading criteria should be periodically reviewed for all analytes that require PT for continued clinical relevance or when other relevant information becomes available.	Addressed in proposed PT rule in development.
September 1-2, 2010	Proficiency Testing	Criteria for Acceptable Performance – 3. Information gathered during the phase-in process for newly required PT should be used to scientifically establish grading criteria.	Addressed in proposed PT rule in development.

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September 1-2, 2010	Proficiency Testing	Criteria for Acceptable Performance – 4. An indeterminate category should be considered an acceptable answer for certain analytes when applicable.	Addressed in proposed PT rule in development.
September 1-2, 2010	Proficiency Testing	Criteria for Acceptable Performance – 5. Peer grouping should be retained when appropriate as a component of the grading criteria.	Addressed in proposed PT rule in development.
September 1-2, 2010	Proficiency Testing	Criteria for Acceptable Performance – 6. Definition of the term "Peer Group" for possible inclusion in the regulations: A group of laboratories whose testing process utilizes similar instruments, methodologies, and/or reagent systems.	Addressed in proposed PT rule in development.
September 1-2, 2010	Proficiency Testing	Criteria for Acceptable Performance – 7. All vendors involved in the production of PT material need to work to minimize matrix effects.	Addressed in proposed PT rule in development.
September 1-2, 2010	Proficiency Testing	Criteria for Acceptable Performance – 8. Designations for PT samples being ungradable (reason codes) should be clarified to distinguish between situations when there are too few participants to grade and sufficient number of participants but consensus is not reached.	Addressed in proposed PT rule in development.
September 1-2, 2010	Proficiency Testing	Microbiology PT – 9. A system for categorizing levels of service must be maintained in the regulations to help laboratories determine what PT they need to perform and assist surveyors in monitoring PT performance and patient testing.	Addressed in proposed PT rule in development.
September 1-2, 2010	Proficiency Testing	Microbiology PT – 10. Laboratories need to declare their patient reporting practices for organisms included in each PT challenge. However, PT programs may only gather this information as it is the inspecting agency's responsibility to review and take action if necessary.	Addressed in proposed PT rule in development
September 1-2, 2010	Proficiency Testing	Microbiology PT – 11. The regulations need to include for all microbiology subspecialties, as applicable, stain(s), susceptibility and resistance testing, antigen and/or toxin detection, and microbial identification or detection.	Addressed in proposed PT rule in development.
September 1-2, 2010	Proficiency Testing	Microbiology PT – 12. Require PT for a generic list of organisms in each subspecialty. For example, in bacteriology the groups listed should include gram-negative bacilli, gram-positive bacilli, gram-negative cocci, and gram-positive cocci.	Addressed in proposed PT rule in development.

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September 1-2, 2010	Proficiency Testing	Microbiology PT – 13. For PT, patient histories and source should be provided, however this information should not preclude the laboratory from performing PT.	Addressed in proposed PT rule in development.
September 1-2, 2010	Proficiency Testing	Microbiology PT – 14. PT results for Gram stains should include both stain reaction and morphology.	Addressed in proposed PT rule in development.
September 1-2, 2010	Proficiency Testing	Microbiology PT – 15. Lower the mixed culture requirement from 50% to 25% for PT challenges of both sample types (those that require laboratories to report only the principal pathogen and those that require laboratories to report all organisms present).	Addressed in proposed PT rule in development.
September 1-2, 2010	Proficiency Testing	Microbiology PT – 16. Required PT for antimicrobial susceptibility and/or resistance testing should be increased to two challenges per event for a total of six challenges per year in bacteriology and should include one gram-positive and one gram-negative organism in each event.	Addressed in proposed PT rule in development.
September 1-2, 2010	Proficiency Testing	Microbiology PT – 17. PT should be required for laboratories that perform susceptibility and/or resistance testing in all microbiology subspecialties. It should include two challenges per event for a total of six challenges per year and should include resistant organisms.	Addressed in proposed PT rule in development.
September 1-2, 2010	Proficiency Testing	Microbiology PT – 18. PT for direct antigen testing should be required for all subspecialties.	Addressed in proposed PT rule in development.
September 1-2, 2010	Proficiency Testing	Microbiology PT – 19. Retain the five required challenges per event and 80% required consensus for grading.	Addressed in proposed PT rule in development.
September 1-2, 2010	Proficiency Testing	Microbiology PT – 20. All PT programs should be required to provide CMS with the overall score for each subspecialty, with a line item underneath that includes a score on the individual PT tests or procedures that comprised the subspecialty score - such as stain(s), susceptibility and resistance testing, antigen and/or toxin detection, and microbial identification and detection.	Addressed in proposed PT rule in development.

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September 1-2, 2010	Proficiency Testing	PT Referral – 21. Distinguish acceptable "PT referral" from unacceptable PT referral with the "intent to defraud" in regulations at §493.801(b)(4) allowing CMS more flexibility in imposing sanctions on laboratories.	CMS addressed PT referral in two rules that defined hierarchical actions and clarified terminology. (CMS-1443-FC, CMS-3267-F)
September 1-2, 2010	Proficiency Testing	PT Referral – 22. Designation of acceptable PT referral would allow laboratories to treat PT exactly as patient samples and perform reflex or referral testing when it is included in their standard procedure for patients.	CMS addressed PT referral in two rules that defined hierarchical actions and clarified terminology. (CMS-1443-FC, CMS-3267-F)
September 1-2, 2010	Proficiency Testing	PT Referral – 23. Laboratories should provide documentation to the referral laboratory on the nature of the referral. Referral laboratories should not be penalized.	CMS addressed PT referral in two rules that defined hierarchical actions and clarified terminology. (CMS-1443-FC, CMS-3267-F)
February 9-10, 2010	Miscellaneous	Create an electronic healthcare record (EHR) workgroup tasked with writing a work statement that includes specific issues and recommendations for stakeholders to address. The Committee requested updates regarding the progress of the identified issues in future meetings.	The Communication in Informatics workgroup met in July 11-12, 2012. Updates on EHR implementation have been given at CLIAC meetings since 2011.
February 9-10, 2010	Genetic Testing	Accept the Biochemical Genetic Testing (BGT) Workgroup report with changes as discussed and approved by the Committee.	Based on CLIAC recommendations, good laboratory practices for biochemical genetic testing and newborn screening were published on April 6, 2012 in the *Morbidity and Mortality Weekly Report: Recommendations and Reports MMWR:R&R,* Vol. 61, No. RR-03 and available at: http://www.cdc.gov/mmwr/pdf/rr/rr6102.pdf.
February 9-10, 2010	Genetic Testing	A recommendation was passed stating CLIAC recognizes that there are some rare biochemical genetic tests which are needed for patient care, but are not currently offered in CLIA-certified laboratories. CLIAC requests that CMS and the Office of Rare Diseases Research at NIH identify specific test gaps that exist today and seek support from the Office of Rare Diseases Research to set up these tests in CLIA-certified laboratories. This could range from assisting laboratories which currently offer these tests to obtain CLIA certification to setting up these tests in existing CLIA laboratories.	With collaboration and input from CDC, the NIH office of Rare Disease Research established a "Collaboration, Education, and Test Translation (CETT)" program during 2003-2008 to facilitate development of rare disease tests in CLIA-certified laboratories.

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September 2-3, 2009	Waived Testing	CMS should survey each Certificate of Waiver (CW) laboratory to: 1) determine which tests they perform, 2) identify who performs the testing, 3) verify that all testing personnel have been trained and shown to be competent for each test they perform, and 4) verify that laboratory has a copy of the manufacturer's current instructions for the test, and that testing personnel follow these instructions when performing testing. A pilot study of a subset of CW laboratories should be conducted prior to extending the survey to all CW laboratories.	CMS conducts educational surveys of 2% of waived testing sites every year. Accreditation agencies also survey some waived testing sites. Sufficient resources are not available to allow CMS to survey all Certificate of Waiver testing sites.
February 4-5, 2009	Miscellaneous	Convene a workgroup to identify issues, currently available routes, and gaps in translating research testing into CLIA certified clinical laboratories.	CDC convened a workgroup to consider next generation sequencing (NGS) and its implementation in clinical laboratories. CDC established the Next Generation Sequencing-Standardization of Clinical Testing (Nex-StoCT) Workgroup in April 2011 to develop guidance for implementing NGS into clinical settings. The guidelines that resulted from the Workgroup deliberations were published in *Nature Biotechnology in* November 2012 and available at: http://www.nature.com/nbt/journal/v30/n11/full/nbt.2403.html. An update was provided to CLIAC on March 2, 2013.
September 11-12, 2008	Waived Testing	Conduct a study to gather data about the impact of waived testing on patient outcomes, clinician behavior, and other similar issues.	CDC funded a study "Improved Waived Testing Performance and Outcomes through Partnerships" which is currently in progress.
September 11-12, 2008	Proficiency Testing	Establish a workgroup to examine and provide suggestions regarding the need for revisions to the CLIA requirements for proficiency testing (PT).	The PT Workgroup met on March 10, 2010 and provided input for CLIAC recommendations on September 1-2, 2010.

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September 11-12, 2008	Genetic Testing	Form a workgroup to consider good laboratory practices for biochemical genetic testing (BGT).	CDC and CMS assembled a workgroup of experts to consider good laboratory practices for BGT which met June 1-2, 2009. The workgroup reported to CLIAC on February 9-10, 2010 who recommended good laboratory practices for biochemical genetic testing. These were published on April 6, 2012 in the *Morbidity and Mortality Weekly Report: Recommendations and Reports MMWR:R&R* Vol. 61, No. RR-03 and available at: http://www.cdc.gov/mmwr/pdf/rr/rr6102.pdf.
September 11-12, 2008	Genetic Testing	CLIAC provided recommendations on "Good Laboratory Practices for Molecular Genetic Testing" and recommended they be published in the *Morbidity and Mortality Weekly Report: Recommendations and Reports (MMWR:R&R).*	Based on CLIAC recommendations, CDC published "Good Laboratory Practices for Molecular Genetic Testing" was published on June 12, 2009 in the *Morbidity and Mortality Weekly Report: Recommendations and Reports MMWR:R&R*, Vol. 58, No. RR-06 and available at: http://www.cdc.gov/mmwr/pdf/rr/rr5806.pdf.
June 20-21, 2006	Proficiency Testing	Considering the Cytology Workgroup's proposals, CLIAC provided recommendations for changes to the cytology proficiency testing regulations in the following areas: frequency of testing, number of challenges, categories of challenges and number of challenges per category, grading scheme, retesting, confidentiality, validation, new technology, and test site.	CDC and CMS developed a proposed rule for cytology proficiency testing based on CLIAC's recommendations. Proposed rule published January 16, 2009.

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February 8-9, 2006	Miscellaneous	Form a workgroup comprised of epidemiologists, clinical laboratories, public health laboratories, industry, and government to examine and broadly address issues related to the impact of rapid testing and molecular technology on public health.	A workgroup comprised of stakeholders including epidemiologists, clinical labs, public health labs, industry and government, met on November 2, 2006 to consider the impact of rapid and molecular tests for infectious disease agents on public health. Workgroup reported to CLIAC on February 14, 2007.
February 8-9, 2006	Proficiency Testing	Convene CLIAC in June 2006 to consider the Cytology Workgroup's report and make recommendations for changes to the cytology proficiency testing regulations.	CLIAC met June 20-21, 2006, and provided recommendations for revisions to the CLIA cytology proficiency testing requirements. Proposed rule was published January 16, 2009.
September 7-8, 2005	Miscellaneous	Create a laboratory companion document to accompany the CLSI document currently under development for manufacturers addressing validation of risk mitigation.	CLSI published a Laboratory Guidance Document (EP23); Laboratory Quality Control Based on Risk Management. No manufacturers' document was published.
September 7-8, 2005	Proficiency Testing	Convene a cytology workgroup to evaluate updated comments from professional organizations and the public and address potential changes to cytology proficiency testing regulations.	Cytology Workgroup comprised of representatives from professional organizations, experts in the field, practicing pathologists, and cytologists met March 28-29, 2006, to address potential changes to cytology proficiency testing regulations. The Workgroup considered current practices and new technology in developing their options for regulatory revision, and reported to CLIAC on June 20-21, 2006.

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February 16-17, 2005	Waived Testing	Provide recommendations for good laboratory practices for waived testing.	CLIAC provided recommendations for good laboratory practices for waived testing which were published November 11, 2005, in the *Morbidity and Mortality Weekly Report: Recommendations and Reports MMWR:R&R,* Vol.54, No. RR-13 and available at: http://www.cdc.gov/mmwr/PDF/rr/rr5413.pdf.
February 16-17, 2005	Proficiency Testing	Consider revising the cytology PT regulations based on updated comments from professional organizations and the public to reflect current practice, evidence-based guidelines, and anticipated changes in technology.	Discussed at the September 2005 CLIAC meeting during which a workgroup reported to CLIAC on June 20-21, 2006 and CLIAC provided recommendations to CMS and CDC. Cytology PT proposed rule published January 16, 2009.
September 22-23, 2004	Miscellaneous	Send letter written by Chair, on behalf of the Committee, to CMS supporting continuing the CMS COW surveys beyond 2004.	Ms. Yost notified the Chair that CMS had received funding to continue the COW surveys in 2005 and a letter from CLIAC to CMS was not needed.
February 11-12, 2004	Waived Testing	Convene a workgroup, chaired by Dr. Foucar and Dr. Schwartz, to investigate the feasibility and process for publishing CMS waived laboratory survey data in CDC's MMWR.	Workgroup comprised of physicians, nurses, laboratorians, manufacturers, distributors, and government representatives met on January 12, 2004, and considered options for publication of CMS' waived laboratory survey data and best practice guidelines for waived testing. Recommendations for good laboratory practices for waived testing and CMS survey summaries published November 11, 2005, in *Morbidity and Mortality Weekly Report: Recommendations and Reports MMWR:R&R*, Vol. 54, No. RR-13 and available at: http://www.cdc.gov/mmwr/PDF/rr/rr5413.pdf.

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February 11-12, 2004	Waived Testing	Based on CLIAC Waiver Workgroup Report, the Committee provided recommendations for development of criteria and oversight guidelines for waived testing to FDA and shared these recommendations with AdvaMed.	Recommendations sent to FDA and AdvaMed on April 8, 2004.
September 17-18, 2003	Waived Testing	Convene a Waiver Workgroup of key stakeholders, chaired by Dr. Goldsmith, to review the testing concerns, data on the process of waiver determination and performance of waived tests, and any other relevant information; report to CLIAC the Workgroup's recommendations regarding appropriate changes to the waiver determination process and oversight of waived tests.	Workgroup comprised of federal agencies, industry, laboratorians, physician office laboratories, CLIAC, and other stakeholders met on January 16, 2004, to consider suggestions for changes to the waiver determination process and oversight of waived tests. Waiver workgroup reported to CLIAC on February 11, 2004.
September 11-12, 2002	Waived Testing	Send letter to the Secretary, HHS, expressing the Committee's concerns related to the possible waiver of rapid HIV tests from the CLIA regulations. CLIAC suggested/recommended the following: (1) appropriate oversight, training, QA, QC, and PT are needed for even the simplest HIV testing device, (2) careful review of objective evidence of test performance by waived testing personnel in waived settings is needed before a rapid HIV device is considered for waiver, and (3) the limited public health certificate exception under CLIA would allow these tests to be used without compromising public health.	Letter sent by CLIAC on September 12, 2002.
January 30-31, 2002	Miscellaneous	In response to CAP request, consider letter to Secretary, HHS, regarding apparent undue burden of the proposed regulations implementing the Health Insurance Portability Accountability Act (HIPAA) on deemed laboratory accreditation organizations acting on behalf of CMS, but obtain CDC/CMS legal counsel review prior to proceeding.	Decision made to not send a letter since original comment period had closed and another HIPAA NPRM was pending publication (published March 27, 2002).
January 30-31, 2002	Miscellaneous	Include breath, when derived from the human body and tested in a laboratory as defined by CLIA, as a specimen source under CLIA.	Pending possible revision of CMS's CLIA implementation policy.
January 30-31, 2002	Personnel	Delete or at least modify the proposed high complexity laboratory director qualification requirement at 493.1443(b)(3)(iii) in the 12/28/01 NPRM to require a more formal mechanism for documenting laboratory expertise.	Deleted in the regulations published in the *Federal Register* on January 24, 2003.
January 30-31, 2002	Waived Testing	Readdress CLIAC's June 8, 2001 letter to FDA (providing the Committee's recommendations relative to FDA's Draft Waiver Guidance) to the Secretary, HHS, as recommendations to be used in rule-making relative to the waiver review criteria and processes.	Letter sent by CLIAC on January 31, 2002.

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January 30-31, 2002	Miscellaneous	Send letter to Secretary, HHS, expressing CLIAC's support of the National Laboratory System.	Letter sent by CLIAC on April 10, 2002.
May 30-31, 2001	Waived Testing	Develop statement reflecting concerns about waiver of rapid human immunodeficiency virus tests.	Statement presented at FDA Blood Products Advisory Committee on June 14, 2001.
February 7-8, 2001 and May 30-31, 2001	Waived Testing	Provide comments to FDA on the Draft Waiver Guidance.	Comments on all aspects of Draft Waiver Guidance verbally presented to FDA representatives on February 7-8, 2001 and May 30, 2001. Letter containing all CLIAC comments sent to FDA on June 8, 2001.
February 7-8, 2001	Genetic Testing	Accept the Genetic Testing Workgroup's evaluation of comments received to the 5/4/00 Notice of Intent (NOI) and include the recommendations in a proposed genetic testing rule.	September 2008 CLIAC meeting: CMS determined existing enforcement is sufficient and provided an action plan in lieu of creating a Genetic Testing specialty.
February 7-8, 2001	Miscellaneous	Develop letter expressing CLIAC support for appropriate containment of wild poliovirus and the HHS survey to be distributed January 2002 identifying laboratories that retain wild poliovirus infectious materials, and the notification to these laboratories to implement biosafety measures.	Letter sent to Dr. Walter R. Dowdle, National Center for Infectious Diseases, CDC, February 8, 2001.
September 27-28, 2000	Waived Testing	Send letter to Secretary, HHS, requesting opportunity to provide comments on waiver process and recommend FDA follow the guidelines for waiver approval published in the September 1995 proposed rule.	Letter sent by CLIAC on September 28, 2000.
April 5-6, 2000	Personnel	Send letter to Secretary, HHS, regarding crisis caused by laboratory workforce shortages.	Letter sent by CLIAC on May 16, 2000.
September 22-23, 1999	Genetic Testing	The Secretary's Advisory Committee on Genetic Testing (SACGT) should formally review the CLIAC recommendations for genetic testing in making decisions.	Recommendations were discussed with SACGT. SACGT requested the Asst. Secretary for Health to expedite publication of the NOI. NOI published May 4, 2000.
September 16-17, 1998	Genetic Testing	Revise the regulations to add definitions and requirements specific for genetic testing for each phase of testing (pre-analytic, analytic, post-analytic) and globally for all phases, where applicable.	Published in the *Federal Register* on May 4, 2000 as a NOI to solicit comments on CLIAC recommendations. September 2008 CLIAC meeting: CMS determined existing enforcement is sufficient and provided an action plan in lieu of creating a Genetic Testing specialty.

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September 16-17, 1998	Miscellaneous	Require that embryo laboratory procedures determined to be tests be under the purview of CLIA.	CMS has determined that it will not cover embryo lab procedures. Some are strictly product evaluation which isn't covered by CLIA. Others are clinical and in the scope of the practice of medicine and therefore not in CLIA.
August 30-31, 1995	Quality Control	Revise requirements for certain microbiology reagents to require QC testing per lot rather than daily QC testing.	Included in regulations published in the *Federal Register* on January 24, 2003.
August 30-31, 1995	Quality Control	Require laboratories to document the basis on which they establish the appropriateness of the quality control limits using acceptable protocols.	Required in QC regulations.
August 30-31, 1995	Quality Control	Include verification of accuracy, precision and reportable range as minimum core requirements for method verification for all laboratories.	Included in regulations published in the *Federal Register* on January 24, 2003.
September 27-28, 1994	Proficiency Testing	Lower the consensus required for grading all tests except immunohematology, hematology blood cell identification, and microbiology organism identification and stain reactions from 90% to 80% based on the PT providers' choice of referee laboratories or peer groups.	Included in regulations published in the *Federal Register* on January 24, 2003. However, no exceptions were made for hematology blood cell identification, microbiology organism identification and stain reactions.
September 27-28, 1994	Proficiency Testing	Lower the consensus required for grading microbiology organism identification and stain reactions from 90% to 80% based on the results of referee laboratories.	Included in regulations published in the *Federal Register* on January 24, 2003. However, consensus required for grading was also lowered from 90% to 80% based on the results of peer groups.

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December 13-14, 1993	Proficiency Testing	Pursue legislative and/or regulatory changes so that cytology proficiency testing (PT) applies to laboratories not individuals, evaluate alternative media for cytology PT, and encourage development of private and state-administered glass slide PT programs.	Statutory revision required to eliminate PT of cytology personnel. Computer-based models have been developed and pilot tested through cooperative agreements with CDC. Screening performance has been compared with performance on glass slide and computer-based PT programs (contract). Study conducted in Maryland to compare performance on glass slide test to computer-based test performance. Publication: Gagnon M, Inhorn S, Hancock J, Keller B, Carpenter D, Merlin T, Hearn T, Thompson, P and Whalen R. Comparison of Cytology Proficiency Testing Glass Slides vs. Virtual Slides. Acta Cytologica vol 48 No. 6, November-December 2004.
December 13-14, 1993	Miscellaneous	Reconsider establishing the accurate and precise technology (APT) subcategory of testing, since it may not provide sufficient regulatory relief to laboratories; at minimum, publish APT as a proposed rule soliciting public comments on the addition of the subcategory and the proposed requirements.	Notice of Proposed Rulemaking (NPRM) published in the *Federal Register* on Sept. 15, 1995. NPRM withdrawn in the "Unified Agenda of Regulatory and Deregulatory Action" published in the *Federal Register* on April 26, 1999.
December 13-14, 1993	Personnel	Include doctoral scientists who were board eligible on February 28, 1992 as personnel qualified to serve as clinical consultants.	Board eligible candidates as of February 28, 1992 should have obtained board certification.
August 12, 1993	Personnel	Do not use board certification as the standard of competency/qualification for PPM and do not accept PPM specialty subcategories.	CLIA regulations do not include these provisions.
August 12, 1993	Waived Testing	Require that all tests, including any cleared by the FDA for home use, meet the CDC proposed guidelines for waiver.	On November 9, 1997, Congress passed the FDA Modernization Act which revised the CLIA law to require that any test approved by the FDA for home use be waived under CLIA. As a result, test systems cleared by the FDA for home use are automatically waived.

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August 12, 1993	Waived Testing	Clarify criteria for waiver (eliminate 'risk of harm' as a criterion for waiver, revise criteria to include 'simple laboratory tests and examinations which have an insignificant risk of reducing an erroneous laboratory test result') and re-evaluate tests currently on the waived list.	Clarifications to the criteria for waiver and proposal to reevaluate currently waived tests included in the proposed regulation published in the *Federal Register* on Sept. 13, 1995.
August 12, 1993	Test Categorization	Include fecal leukocyte, wet mounts of prostatic secretions, qualitative semen analysis in PPM.	Included in regulations published in the *Federal Register* on April 24, 1995.
May 26-27, 1993	Personnel	Clarify bachelor's degree for moderate complexity laboratory director and technical consultant and for high complexity general supervisor and technical supervisor i.e., define and specify equivalent qualifications for the bachelor's degree.	Requires revisions to the personnel regulations. Not on CMS schedule.
May 26-27, 1993	Personnel	Revise high complexity testing personnel qualifications to define credentials equivalent to an associate degree in medical laboratory technology or laboratory science, includes 1 year of laboratory training in all laboratory specialties or 3 months in each specialty testing is performed. Also, prohibit labs from hiring high school graduates for high complexity testing as of effective date of regulations.	Included in regulations published in the *Federal Register* on April 24, 1995. **Note:** High school graduates could be hired until 8/31/97; however, those hired after 1/19/93 require on-site supervision. Those hired after 4/24/95 must have obtained an associate degree or equivalent by 9/1/97.
May 26-27, 1993	Personnel	Revise general supervisor requirements to prospectively require a bachelor's degree with a 1 year laboratory training component or 3 months experience in each specialty supervised.	Requires revisions to the personnel regulations. Not on CMS schedule.
May 26-27, 1993	Personnel	Do not permit individuals, who qualify as laboratory directors of high complexity testing, to qualify as clinical consultants in lieu of other requirements.	No action required (current regulations do not include such a provision).
May 26-27, 1993	Personnel	Use interpretive guidelines instead of regulations to list various qualifications (including physician board certifications) in the personnel requirements.	List of approved certification boards removed from the regulations published in the *Federal Register* on January 24, 2003, and included in revisions to the SOM interpretative guidelines.
May 26-27, 1993	Personnel	Qualify respiratory therapists to serve as blood gas general supervisors and high complexity testing personnel.	Requires revisions to the personnel regulations. Not on CMS schedule.

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May 26-27, 1993	Personnel	"Grandfather" individuals serving as a general supervisor on or before 9/1/92 with: -- associate degree in laboratory science, medical technology, or equivalent + 2 yrs. exp. -- successful completion of accredited laboratory training program or military training program + 2 yrs. exp. -- High School + documented training + 10 yrs. experience (includes 6 yrs. supervisory).	Included in regulations published in the *Federal Register* on April 24, 1995.
May 26-27, 1993	Personnel	Qualify neurologists with specialized training and board certification as technical supervisors, general supervisors and testing personnel of neuromuscular histology.	The American Academy of Neurology Committee for Neuromuscular Pathology's documentation of the training and qualifications of neurologists has been approved as a mechanism to qualify neurologists to perform neuromuscular examinations and serve as supervisors of laboratories performing these examinations. Included in regulations published in the *Federal Register* on January 24, 2003.
May 26-27, 1993	Personnel	Qualify individuals with doctoral, master's, bachelor's degrees and appropriate experience as technical supervisors of immunohematology.	Requires revisions to the personnel regulations. Not on CMS schedule.
May 26-27, 1993	Personnel	"Grandfather" individuals qualified under the March 1990 rule as technical supervisors.	No action required ("grandfather" provision for technical supervisor not included in 1992 final rule).
May 26-27, 1993	Waived Testing	Waive Chemtrak Single Analyte Cholesterol Accumeter.	Categorized as waived, manufacturer notified March 17, 1995, included in the test categorization notice published in the *Federal Register* on July 8, 1996.
May 26-27, 1993	Personnel	Add midlevel practitioners to the individuals qualified to perform PPM procedures. Change the name of the PPM subcategory from “physician-performed" to "provider-performed" microscopy.	Included in regulations published in the *Federal Register* on April 24, 1995. **Note:** Dentists also added.
February 17-18, 1993 and May 26-27, 1993	Test Categorization	Include examination of nasal smears for granulocytes in PPM.	Included in regulations published in the *Federal Register* on April 24, 1995.

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February 17-18, 1993	Personnel	Qualify individuals, who as of 9/1/94 are graduates of a laboratory training or 50 week military training program, to perform high complexity testing without supervisory review.	Included in regulations published in the *Federal Register* on April 24, 1995. **Note:** No supervisory review regardless of hire date.
February 17-18, 1993	Personnel	Permit high complexity testing personnel with high school diplomas and documented training as of 9/1/92 to continue testing without an associate degree indefinitely, provided that testing is reviewed within 24 hours.	Included in regulations published in the *Federal Register* on April 24, 1995. **Note:** High school graduates with documented training hired prior to 4/24/95 do not have to obtain an associate degree or equivalent. On-site supervision is required for those hired between 1/19/93 and 4/24/95.
February 17-18, 1993	Waived Testing	Do not add rapid strep test to the list of waived tests.	Several rapid strep tests have met the CLIA requirements for waiver and are categorized as waived. The list of tests waived may be accessed via Internet at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm.
February 17-18, 1993	Test Categorization	Do not include Gram stain, Tzanck test and rapid strep tests in PPM.	No action required. These procedures do not meet the criteria for categorization as a PPM procedure.
February 17-18, 1993	Waived Testing	Develop definitive criteria for categorizing tests as waived and declare a moratorium on further review of tests for waived status until the definitive criteria are developed.	Declared a moratorium on waiver determinations. Moratorium lifted in December 1994 when draft guidelines containing clarified waiver criteria and process for reviewing waiver requests issued to all manufacturers of moderate complexity test systems.
February 17-18, 1993	Test Categorization	Recategorize the HDL-cholesterol performed on the Kodak Ektachem DT 60 from high to moderate complexity and have the Kodak Ektachem DT 60 serve as an Aindex@ test system for the review of similar HDL cholesterol test systems.	Included in the test categorization notice published in the *Federal Register* on July 26, 1993.
October 28-29, 1992	Waived Testing	Add Hemocue hemoglobin testing to the list of waived tests.	Added "hemoglobin by single analyte instrument…" to the waived test list in regulations published in the *Federal Register* on January 19, 1993.

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October 28-29, 1992	Test Categorization	Categorize urethral/cervical Gram stains as moderate complexity. Categorize Gram stains from all other sources as high complexity.	Included in the test categorization notice published in the *Federal Register* on July 26, 1993.
October 28-29, 1992	Test Categorization	Consider the isolation, identification, and susceptibility of organisms transferred from culture as a single test and categorize as high complexity.	Included in the test categorization notice published in the *Federal Register* on July 26, 1993.
October 28-29, 1992	Miscellaneous	Create a subcategory of moderate complexity, physician-performed microscopy procedures (PPM) that does not require routine inspections. Include wet prep, KOH prep, post-coital exam, Fern test, pinworm test and urine microscopic exams in PPM.	Included in regulations published in the *Federal Register* on January 19, 1993.