CLINICAL LABORATORY IMPROVEMENT ADVISORY COMMITTEE (CLIAC) RECOMMENDATIONS TABLE

Consistent with Executive Order (E.O.) 14217 entitled "Commencing the Reduction of the Federal Bureaucracy," CLIAC was declared terminated on March 31, 2025, by the Secretary of the United States Department of Health and Human Services (HHS).

MEETING DATE	CATEGORY	CLIAC RECOMMENDATION
November 6-7, 2024	The Biosafety Workgroup Report	The Committee deliberated, voted, and approved the following recommendations based on *The Biosafety Workgroup Report* topic. **Recommendation 1:** CLIAC recommends revising the CLIA requirements to include general biosafety training as part of the competency requirements for testing personnel.
November 6-7, 2024	The Biosafety Workgroup Report	**Recommendation 2:** CLIAC recommends that a standardized definition of a biosafety risk assessment should be developed and added to 42 CFR 493.2. a. The language used to define a biosafety risk assessment should cover general biosafety risk assessment processes, including hazard assessment, mitigation, management, and performance monitoring. i. Part of the general biosafety risk assessment could include a request, if available and provided, and written equipment disinfection instructions and practices, preferably before purchase. ii. Laboratories should consider the provision of written disinfection instructions and practices before purchasing equipment.
November 6-7, 2024	The Biosafety Workgroup Report	**Recommendation 3:** CLIAC recommends that CDC provide educational tools and resources on how laboratories can develop and perform biosafety risk assessments.
November 6-7, 2024	The Biosafety Workgroup Report	**Recommendation 4:** CLIAC recommends that it is best practice that laboratories should be required to perform a biosafety risk assessment on all instrumentation currently in use. Before implementation, laboratories should consider biosafety risks when purchasing new equipment and must complete a risk assessment (analogous to analytic verification).
November 6-7, 2024	The Biosafety Workgroup Report	**Recommendation 5:** CLIAC recommends that 42 CFR 493.1804(a)(2) should be expanded to clarify that laboratory workers and, in turn, the general population should be safeguarded.
November 6-7, 2024	The Next Generation Sequencing Workgroup Report	The Committee deliberated, voted, and approved the following recommendations based on the topic of *The CLIAC Next Generation Sequencing Workgroup Report*. **Recommendation 6:** CLIAC recommends that the CLIA testing personnel qualifications for laboratories performing high complexity testing should be modified to add a qualification route for the responsibilities of bioinformaticians, which are not burdensome for laboratories.

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November 6-7, 2024	The Next Generation Sequencing Workgroup Report	**Recommendation 7:** CLIAC recommends that a CLIA personnel carve-out be created to allow individuals who perform bioinformatics data analysis to qualify under CLIA, similar to how the current blood gas analysis carve-out is at § 493.1461 and § 493.1489. This carve-out should be developed for all CLIA-required personnel in the clinical laboratory who are involved in bioinformatics.
November 6-7, 2024	The Next Generation Sequencing Workgroup Report	**Recommendation 8:** CLIAC recommends using the existing CLIA personnel roles (testing personnel, general supervisor, technical supervisor, and director), along with the experience and degree requirements, as a framework to build upon. • The bioinformatician qualification paths may include requirements for bioinformatics beyond biological and data sciences that may consist of specialized areas such as bioinformatics, genetics, statistics, statistical genetics, computer science, software engineering, biochemistry, etc. • A carve-out would also be needed for general supervisors, technical supervisors, and laboratory directors who oversee bioinformatics activities in laboratories performing high complexity testing using the workgroup's proposal for bioinformatics testing personnel as the baseline.
November 6-7, 2024	Cybersecurity Requirements in the Clinical Laboratory	The Committee deliberated, voted, and approved the following recommendations based on the topic of *Cybersecurity Requirements in the Clinical Laboratory*. **Recommendation 9**: CLIAC recommends a regulation that requires laboratories to have a documented cybersecurity plan. This includes defining what cybersecurity means for the clinical laboratory. CDC should create educational tools and resources for laboratories related to developing a cybersecurity plan.
November 6-7, 2024	Cybersecurity Requirements in the Clinical Laboratory	**Recommendation 10**: CLIAC recommends updating the existing CLIA regulations to reflect modern cybersecurity and information management issues.
November 6-7, 2024	Proficiency Testing: Determination of Clinically Relevant Range of Values	The Committee deliberated, voted, and approved the following recommendations based on the topic of *Proficiency Testing: Determination of Clinically Relevant Range of Values*. **Recommendation 11**: CLIAC recommends that the CLIA requirements for proficiency testing programs be updated to include consideration for analytical measurement ranges, including those values that may be medically relevant, if possible, for regulated analytes.
November 6-7, 2024	Utilization of Remote Technology for Competency Assessments	The Committee deliberated, voted, and approved the following recommendations based on the topic of the *Utilization of Remote Technology for Competency Assessments*. **Recommendation 12**: CLIAC recommends that CMS allow remote assessment to be utilized in the direct observation component of competency assessment.

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April 10, 2024	The Applicability of CLIA Personnel Requirements to Preanalytic Testing	The Committee deliberated, voted, and approved the following recommendations based on *The Applicability of CLIA Personnel Requirements to Preanalytic Testing* topic. **Recommendation 1**: CLIAC recommends that the CLIA laboratory director's responsibilities include determining the required competency of personnel who perform preanalytic phase processes, including documentation.
April 10, 2024	The Role of Artificial Intelligence and Machine Learning in the Clinical Laboratory	The Committee deliberated, voted, and approved the following recommendations based on *The Role of Artificial Intelligence and Machine Learning in the Clinical Laboratory* topic. **Recommendation 2**: CLIAC recommends creating a workgroup to explore the current and future intersection between artificial intelligence and machine learning in the clinical laboratory, specifically regarding implementing and deploying tools in the clinical laboratory.
April 10, 2024	The Use of Clinical Standards to Improve Laboratory Quality	The Committee deliberated, voted, and approved the following recommendations based on *The Use of Clinical Standards to Improve Laboratory Quality* topic. **Recommendation 3**: CLIAC recommends CMS/CDC/FDA to engage professional societies (e.g., harmonization.net) to encourage test developers to participate in existing clinical standardization programs.
April 10, 2024	The Use of Clinical Standards to Improve Laboratory Quality	The Committee deliberated, voted, and approved the following recommendations based on *The Use of Clinical Standards to Improve Laboratory Quality* topic. **Recommendation 4**: CLIAC recommends that CDC create a marketing campaign to raise awareness of standardization/harmonization efforts and their benefits.
November 8-9, 2023	CLIA Regulations Assessment Workgroup	The Committee deliberated, voted, and approved the following recommendations based on The CLIA Regulations Assessment Workgroup Report. **Recommendation 1**: CLIAC recommends that CMS update CLIA to recognize histotechnicians, histotechnologists, and pathology assistants as testing personnel and define the educational requirements for each personnel category.
November 8-9, 2023	Efforts to Address the CLIA Top 10 Laboratory Deficiencies	The Committee deliberated, voted, and approved the following recommendations based on *The Efforts to Address the CLIA Top 10 Laboratory Deficiencies* topic. **Recommendation 2**: CLIAC recommends that CMS engage Accrediting Organizations to increase the granularity of data related to the CLIA top 10 deficiencies.
November 8-9, 2023	Efforts to Address the CLIA Top 10 Laboratory Deficiencies	**Recommendation 3**: CLIAC recommends that CDC and CMS engage with professional organizations and hospital and facility agencies to incorporate CLIA regulation requirements into the required training programs for hospital and laboratory quality organizational leaders.

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November 8-9, 2023	Efforts to Address the CLIA Top 10 Laboratory Deficiencies	**Recommendation 4**: CLIAC recommends that CMS evaluate and consider modifications to the CLIA regulations for competency assessment to simplify the regulations and clarify the procedures while ensuring the competency of laboratory personnel.
November 8-9, 2023	Efforts to Address the CLIA Top 10 Laboratory Deficiencies	**Recommendation 5**: CLIAC recommends that CMS consider requiring interim CLIA self-assessment and documentation of correction of self-identified deficiencies.
November 8-9, 2023	The Role of the Laboratory in Diagnostic and Antibiotic Stewardship	The Committee deliberated, voted, and approved the following recommendations based on *The Role of the Laboratory in Diagnostic and Antibiotic Stewardship* topic. **Recommendation 6**: To expand the influence of the CLIA quality program and strengthen clinical laboratory quality, CLIAC recommends that CMS and CDC develop an educational campaign promoting diagnostic stewardship programs targeting clinical laboratories.
November 8-9, 2023	The Role of the Laboratory in Diagnostic and Antibiotic Stewardship	**Recommendation 7**: CLIAC recommends that CDC and FDA encourage in vitro diagnostics (IVD) manufacturers to harmonize results across different platforms, when possible, to allow for safe aggregation of patient results from other institutions to trend results and reduce duplicate testing.
November 8-9, 2023	The Role of the Laboratory in Diagnostic and Antibiotic Stewardship	**Recommendation 8**: CLIAC recommends updating the CLIA regulations to include blood culture contamination rate monitoring within the laboratory quality management system.
November 8-9, 2023	Standardization of Test Result Communication	The Committee deliberated, voted, and approved the following recommendations based on *The Standardization of Test Result Communication* topic. **Recommendation 9**: CLIAC recommends that HHS require that all transmission of laboratory results throughout the healthcare ecosystem, at a minimum, adhere to the required discrete results defined in laboratory result reports in CLIA.
November 8-9, 2023	Standardization of Test Result Communication	**Recommendation 10**: CLIAC recommends a CLIAC workgroup be formed, including key stakeholders, organizations/agencies from the provider, and health IT communities, to understand the opportunities for enhanced communication of laboratory results and to verify action upon those results.
April 12-13, 2023	CLIA Regulations Assessment Workgroup	The Committee deliberated, voted, and approved the following recommendations (1-29) based on the CLIA Regulations Assessment Workgroup Report on the CLIA Subpart K – Quality Systems for Nonwaived Testing. CLIAC recommends that HHS consider modifying the CLIA Subpart K as follows: **Recommendation 1**: CLIA Subpart K - Quality System for Nonwaived Testing should be updated to reflect past CLIAC recommendations related to remote and distributive testing from April 2022 and November 2022.

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April 12-13, 2023	CLIA Regulations Assessment Workgroup	**Recommendation 2**: The definitions in the CLIA regulations or CMS State Operations Manual (SOM) should be updated to include terms related to the establishment of performance specifications for both qualitative and quantitative tests, including accuracy, precision, analytical sensitivity, and specificity. Information in the SOM should include published professional organization guidelines, as applicable.
April 12-13, 2023	CLIA Regulations Assessment Workgroup	**Recommendation 3**: Subpart K - Quality System for Nonwaived Testing, Analytic Systems should be generalized to address quantitative and qualitative test modalities.
April 12-13, 2023	CLIA Regulations Assessment Workgroup	**Recommendation 4**: The regulations on quality assessment at § 493.1200(b) should be clarified to address the recurrence of problems, "The laboratory's quality systems must include a quality assessment component that ensures continuous improvement of the laboratory's performance and services through ongoing monitoring that identifies, evaluates, resolves, and limits the likelihood of the recurrence of problems."
April 12-13, 2023	CLIA Regulations Assessment Workgroup	**Recommendation 5**: A new standard related to data analysis is needed in Subpart K - Quality System for Nonwaived Testing under General Laboratory Systems, to encompass all data types that can be manipulated to generate a final laboratory test result.
April 12-13, 2023	CLIA Regulations Assessment Workgroup	**Recommendation 6**: Additional information relating to the confidentiality of patient information should be included in § 493.1231 that the laboratory must follow documented policies and procedures to ensure patient confidentially during data transfer to external referral laboratories, remote testing locations, or other entities. This may include cloud-based computing, such as storing confidential data, as appropriate. The laboratory must comply with other Federal laws, including but not limited to the HIPAA Final Security Rule.
April 12-13, 2023	CLIA Regulations Assessment Workgroup	**Recommendation 7**: The specimen identification and integrity regulations under § 493.1232 should be clarified to include a requirement that the laboratory must follow documented policies and procedures for specimen acceptance and rejection.
April 12-13, 2023	CLIA Regulations Assessment Workgroup	**Recommendation 8**: CLIAC recommends that CMS include information related to specimens collected outside of the laboratory's control in the SOM.
April 12-13, 2023	CLIA Regulatory Assessment Workgroup	**Recommendation 9**: The use of "panic or alert values" should be replaced with "critical value" at §§ 493.1241(c)(1), 493.1251(b)(11), 493.1251(b)(13), and 493.1291(g).
April 12-13, 2023	CLIA Regulations Assessment Workgroup	**Recommendation 10**: The specimen labeling requirement at § 493.1241(c)(2) and § 493.1242(a)(3) should be updated to remove "patient name or unique patient identifier…" and include "at least two unique patient-specific identifiers."
April 12-13, 2023	CLIA Regulations Assessment Workgroup	**Recommendation 11**: The procedure manual requirement § 493.1251(a) should be updated to remove the reference to "Textbooks" and replace it with "resource materials reflecting the current standard of care." This change should also be made at § 493.1253(b)(2) to include "…or other materials reflecting the current standard of care."
April 12-13, 2023	CLIA Regulations Assessment Workgroup	**Recommendation 12**: Additional information is needed under the procedure manual requirements under § 493.1251(b) to include information related to data analysis. For example, § 493.1251(b)(3) should consist of data collection and analysis. Examples can be added to the SOM.

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April 12-13, 2023	CLIA Regulations Assessment Workgroup	**Recommendation 13**: The SOM should be updated to include a definition of interfering substances as mentioned in § 493.1251(b)(9).
April 12-13, 2023	CLIA Regulations Assessment Workgroup	**Recommendation 14**: The current use of "Reference intervals (normal values)" should be replaced with "Reference intervals or expected results as appropriate to the test system" at §§ 493.1251(b)(10), 493.1253(b)(1)(ii), 493.1253(b)(2)(vi), 493.1282(b)(iii), and 493.1291(d).
April 12-13, 2023	CLIA Regulations Assessment Workgroup	**Recommendation 15**: The SOM should include examples of reference intervals or expected results as appropriate to the test system for both qualitative and quantitative tests.
April 12-13, 2023	CLIA Regulations Assessment Workgroup	**Recommendation 16**: The CLIA regulations under § 493.1252 or SOM should be updated to include new technologies or testing practices for each specialty or subspecialty, data exchange, analysis, and remote/distributive work requirements. The November 2022 CLIAC recommendation to modify the definition of a "test system" to include "…software algorithms, data exchange and analysis procedures, and other components needed to perform an assay or examination and generate test results and report" should be incorporated into this section.
April 12-13, 2023	CLIA Regulations Assessment Workgroup	**Recommendation 17**: The regulations related to test systems not subject to FDA clearance or approval at § 493.1253(b)(2) should be updated to replace "in-house" with "laboratory developed test" terminology.
April 12-13, 2023	CLIA Regulations Assessment Workgroup	**Recommendation 18**: The CLIA regulations and SOM should be updated to include harmonized definitions for the terms used in § 493.1253(b)(i-vii) so they apply to qualitative and quantitative tests.
April 12-13, 2023	CLIA Regulations Assessment Workgroup	**Recommendation 19**: The SOM should be updated to include more guidance related to calibration verification procedures under § 493.1255(b). This should include clarification between the analytical measurement range and the reportable range.
April 12-13, 2023	CLIA Regulations Assessment Workgroup	**Recommendation 20**: The requirement for including at least a minimal (or zero) value, a midpoint value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system at § 493.1255(b)(2)(ii) is problematic for qualitative assays. The regulations should be clarified for qualitative assays, or the current regulations should be modified to include "as applicable to the test system." Also, many test systems do not have a "zero" value. The regulations should be updated to remove the reference to a "zero" value.
April 12-13, 2023	CLIA Regulations Assessment Workgroup	**Recommendation 21**: The SOM should be updated to include more guidance on control procedures under § 493.1256 for platforms producing multiple results, such as multiplex cartridges, genetic panels, etc.
April 12-13, 2023	CLIA Regulations Assessment Workgroup	**Recommendation 22**: The SOM should be updated to include guidance for tests where two levels of quality control are not beneficial.
April 12-13, 2023	CLIA Regulations Assessment Workgroup	**Recommendation 23**: The specification for thin layer chromatography under § 493.1256(d)(4) should be removed from the CLIA regulations and included in the SOM.

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April 12-13, 2023	CLIA Regulations Assessment Workgroup	**Recommendation 24**: The specialty and subspecialty sections starting § 493.1261 through § 493.1278 should be updated to address outdated regulations and update the regulations to incorporate changes in technology. • Generalized statements should be developed for each specialty and subspecialty section to account for new test technologies and the need for remote test analysis and reporting of test results. • A crosswalk should be performed in these sections with the general considerations section. • The SOM should include information specific to each specialty or subspecialty.
April 12-13, 2023	CLIA Regulations Assessment Workgroup	**Recommendation 25**: The regulations related to immunohematology at § 493.1271(c) should be updated to change "inspected" to "tested." Also, the CLIA regulations at § 493.1271(c)(2) should be updated to "Alarm system testing must be documented."
April 12-13, 2023	CLIA Regulations Assessment Workgroup	**Recommendation 26**: The regulations related to cytology at § 493.1274 should be reevaluated in recognition of the more diverse interpretive workload and practice context.
April 12-13, 2023	CLIA Regulations Assessment Workgroup	**Recommendation 27**: The SOM should be updated to clarify the comparison of test results requirements described under § 493.1281. The update should include the following: • Information on what is considered as the same test using different methodologies or instruments. • Examples of what is considered when something is regarded as the same analyte, e.g., different specimen types, different analytic targets (troponin I versus T or HS troponin), different analytic or therapeutic ranges, tests with different sensitivities, and qualitative versus quantitative tests.
April 12-13, 2023	CLIA Regulations Assessment Workgroup	**Recommendation 28**: The regulations related to the requirement for test records at § 493.1283 should be updated to include patient confidentiality requirements.
April 12-13, 2023	CLIA Regulations Assessment Workgroup	**Recommendation 29**: The regulations related to the requirement for test records at § 493.1283(a) should be updated to include a requirement for specimen collection date and time in accordance with laboratory-specified requirements.
April 12-13, 2023	Certificate for Provider-performed Microscopy Procedures	The Committee deliberated, voted, and approved the following recommendations (30-31) based on the CLIA Certificate of Waiver and Certificate for Provider-performed Microscopy Workgroup report on the CLIA Certificate for Provider-performed Microscopy Procedures topic: **Recommendation 30**: CLIAC recommends that more information is needed about CLIA Certificate for Provider-performed Microscopy Procedure sites and suggests the expansion of the CMS PPM Project.
April 12-13, 2023	Certificate for Provider-performed Microscopy Procedures	**Recommendation 31**: CLIAC recommends that CLIA regulations be modified to implement routine inspection for CLIA Certificate for Provider-performed Microscopy sites.

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April 12-13, 2023	The Laboratory's Role in Advancing Health Equity	The Committee deliberated, voted, and approved the following recommendations on the topic of the laboratory's role in advancing health equity: **Recommendation 32**: CLIAC recommends the formation of a workgroup to determine how the clinical laboratory can contribute to health equity and population health and to closing racial/ethnic inequities in disease conditions with substantive disparities in incidence, prevalence, and outcomes. The scope is to be chronic kidney disease and its contributing factors, including social determinants of health, including examining barriers to closing these inequities.
April 12-13, 2023	The Laboratory's Role in Advancing Health Equity	**Recommendation 33**: CLIAC recommends that the FDA evaluate instruments that cannot implement the CKD-EPI 2021 eGFR race-free equation, standardize the creatinine methods, and report back to CLIAC during the November 2023 meeting.
April 12-13, 2023	The Laboratory's Role in Advancing Health Equity	**Recommendation 34**: CLIAC recommends that the CDC's Division of Laboratory Systems work with partners, such as professional organizations, community groups, and others, to provide outreach and training related to the CKD-EPI 2021 eGFR race-free equation.
November 9-10, 2022	CLIA Regulations Assessment Workgroup	The Committee deliberated, voted, and approved the following recommendations (1-5) based on the CLIA Regulations Assessment Workgroup Report: **Recommendation 1**: The term "materials derived from the human body," as stated in the Clinical Laboratory Improvement Amendments (42 USC 263a), should be defined in CLIA as the patient specimen, including data derived from a human specimen such as images, genetic and protein sequence(s), –omics data, and other data that is used for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings.
November 9-10, 2022	CLIA Regulations Assessment Workgroup	**Recommendation 2**: The definition of a "test system" should be modified in CLIA to include all of the instructions, instrumentation, equipment, reagents, supplies, software algorithms, data exchange, and analysis procedures, and other components needed to perform an assay or examination and generate test results and report.

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November 9-10, 2022	CLIA Regulations Assessment Workgroup	**Recommendation 3:** CLIAC recommends that the following guidelines be used when assessing the applicability of a site's CLIA certificate when evaluating whether remote testing requires an additional CLIA certificate for staff working at a remote location: 1. The CLIA regulations should be revised to allow remote analysis for any CLIA specialty or subspecialty. 2. If a laboratory employee works out of their home or at another remote location performing duties such as data analysis and interpretation associated with that laboratory, then those activities would be covered through an extension of that laboratory's CLIA certificate and do not require disclosure of the address of the remote location. 3. A laboratory's CLIA certificate covers the qualified laboratory personnel when using a secured connection authorized and/or managed by that laboratory to review and report data for test processing remotely.
November 9-10, 2022	CLIA Regulations Assessment Workgroup	**Recommendation 4:** CLIAC recommends a new certificate type for an entity manipulating information received from and returned to the clinical laboratory for inclusion in the patient report or for patient care.
November 9-10, 2022	CLIA Regulations Assessment Workgroup	**Recommendation 5:** CLIAC recommends that FDA include, whenever possible, controls for specimen adequacy, integrity, and human origin for authorization of self-collection devices.
November 9-10, 2022	CLIA Certificate of Waiver	The Committee deliberated, voted, and approved the following recommendation based on the CLIA Certificate of Waiver and Certificate for Provider-performed Microscopy Workgroup report on the CLIA Certificate of Waiver topic: CLIAC recommends that the CLIA law be opened to allow oversight of CLIA Certificate of Waiver testing sites.
November 9-10, 2022	Laboratory Workforce	CLIAC recommends that CDC, CMS, and other federal laboratory partners implement technology alternatives (e.g., virtual reality) to current in-person activities (e.g., training, learning, competency assessment) to meet regulatory requirements (e.g., CMS, OSHA, DOT).
November 9-10, 2022	Laboratory Workforce	CLIAC recommends CDC examine opportunities for funding to support the educational pipeline for the laboratory profession, including but not limited to tuition benefits and loan forgiveness for students and supporting institutions of learning and sites of clinical training with special attention to recruitment and admission of students from minority and underrepresented populations.
November 9-10, 2022	Laboratory Workforce	To improve health equity and public health, CDC should partner with industry and philanthropic organizations to have virtual reality (VR) tools and resources accessible for clinical laboratory training.

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April 13-14, 2022	Remote Selection, Interpretation, and Reporting of Patient Results	Laboratory practice over the last two years has demonstrated the success of remote analysis and interpretation of digital data securely. CLIAC augments its 2019 recommendation that CMS and the U.S. Department of Health and Human Services permanently codify that a laboratory's CLIA certificate covers employees of that laboratory who are performing data analysis and interpretation of digital information under the quality oversight from a primary site when working remotely under the home laboratory's CLIA certificate.
April 13-14, 2022	Laboratory Workforce	Given the current crisis in the staffing of trained and competent laboratory personnel, including regional/local shortages in sufficient personnel to safely operate clinical laboratories to serve their patients as required by law, CLIAC recommends that CDC: • Raise the recognition of laboratory professionals in health care through its outreach, communication, training, and guidance (partnerships with the laboratory science community to increase interest in laboratory careers) • Work with partners to create and expand access to educational content and resources and identify other opportunities to reduce the burden on individual training programs (create and oversee programs for clinical laboratory sciences training programs) • Conduct a workplace survey of laboratory professionals to support and guide critical recruitment and retention activities.
November 3-4, 2021	Next Generation Sequencing	**Recommendation 1**: CLIAC recommends that CDC, CMS, and FDA convene a workgroup to define the scope of practice and the requisite CLIA qualifications for personnel performing bioinformatic data analysis and interpretation to produce test results that inform clinical decision-making. Workgroup topics and needed input: Provide recommendations and cross-reference existing guidelines regarding education, training, experience, and competencies for various bioinformatics levels, for example: • An MS or PhD level individual who provides analytic leadership, tool selection, and database oversight. • A bioinformatics technician who, for example, ensures data files are appropriately formatted for analysis, runs the analysis, and checks for the adequacy of the run. • The skill sets required for the Laboratory Director (MD/DO or PhD) who carries overall responsibility for the clinical laboratory. Seek input from institutions of higher learning (universities) to develop, in concert with clinical laboratories, a curriculum, and training for each level. Engage certifying bodies (e.g., The American Board of Pathology and the American Society for Clinical Laboratory Science Board of Certification) in developing certification or other credentialing opportunities for clinical bioinformaticians who will work in CLIA laboratories.

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November 3-4, 2021	Next Generation Sequencing	**Recommendation 2**: CLIAC recommends that the CDC, CMS, and FDA create a workgroup to review real-world practices as they apply to NGS for: • the end-to-end processing of data, including the acquisition, analysis, and transmittal of data (including the Admission, Discharge, and Transfer (ADT) message, orders, and results) between instruments and health records, including but not limited to electronic communication between the electronic health record (EHR), laboratory information system (LIS) or laboratory information management system (LIMS), and IVD vendors, as well as interoperability between institutions. • quality management systems, including documentation, regarding data security, fidelity, transmission, curation, retention, and retrieval. • validation of software algorithms used to generate interpretations
November 3-4, 2021	Laboratory Data Exchange and Harmonization	**Recommendation 3**: CLIAC recognizes SHIELD's efforts and encourages collaboration with CDC, CMS, FDA, other HHS organizations (e.g., ONC), IVD and EHR vendors, and professional organizations to leverage current standards and fund a phased approach by which specimens, actionable test results, and methods are coded for interoperability. EHR vendors, bioindustry suppliers, and non-profit and commercial laboratories must implement the standard(s) within a specified timeline. HHS should identify an appropriate mechanism for compliance.
April 14-15, 2021	Training and Education	CLIAC recommends that the CDC develop training and educational materials for SARS-CoV-2 self-testing, point-of-care testing, and follow-up care.
October 28-29, 2020	The Partnership between Clinical Laboratories and Public Health	**Recommendation 1:** CLIAC recommends that CDC identify academic and community-based/regional clinical laboratories in distinct geographic regions to diversify the Public-Private Partnership Taskforce, including healthcare organizations as stakeholders, to meet changing regional and community healthcare needs.
October 28-29, 2020	The Partnership between Clinical Laboratories and Public Health	**Recommendation 2**: CLIAC recommends that CDC initiate a study to explore resources needed to develop a comprehensive, extensive laboratory network (for example, enhancing the Laboratory Response Network) that balances moments and areas of excess testing capacity to meet clinical needs during a public health emergency.
October 28-29, 2020	Laboratory Data Exchange	**Recommendation 3:** CLIAC recommends that the Assistant Secretary for Preparedness and Response (ASPR) coordinate a national process to obtain and allocate critical diagnostic clinical laboratory testing resources to manage a public health emergency. Key features of the process include transparency about resource allocation and clearly defined approaches for both public health and clinical laboratories. Public health officials and clinical laboratory representatives need to collaborate to provide information to guide resource decisions. Processes, decisions (with justifications), and data provided by the public health and clinical laboratories and by responsible authorities (for example, public health and elected officials) should be made public.

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October 28-29, 2020	Laboratory Data Exchange	**Recommendation 4**: CLIAC recommends that CDC use funding (for example, the CARES Act, the $500 million for data surveillance and analytical infrastructure) to improve (replace or upgrade) existing laboratory information system infrastructures, such as the Association of Public Health Laboratories (APHL) Informatics Messaging Services (AIMS) platform, to centralize and standardize public health reporting (for example, data clearinghouse or health information exchange). Key attributes include: • Interoperability, • Review of state reporting systems, • Standardization of reporting requirements of public health/clinical laboratories and/or other diagnostic services, • Technical specifications, and • Advantages and challenges of investing in a centralized reporting infrastructure.
October 28-29, 2020	Health Disparities	**Recommendation 5**: CLIAC recommends that CDC develop guidelines for America's laboratories in addressing health disparities, resulting in a national plan to champion laboratory engagement in closing gaps in care that broadly address social determinants of health. CDC should consider: • Expansion of traditional laboratory activities (for example, insights from commonly ordered diagnostic tests). • New non-traditional roles of diagnostic and public health laboratories. • Process for how the laboratory community can best engage with clinical colleagues to close gaps in care. • Establishment of key metrics to demonstrate that laboratories are contributing to addressing health disparities across the total testing process. • Identification of potential roles for different laboratories in the United States: public health, independent, academic, and community hospital laboratories. • Establishment of a public-private partnership among federal, state, and local governments, professional societies, and care providers (for example, federally qualified healthcare centers) to ensure the development and dissemination of a national plan. • A study to identify embedded inherent bias that involves current test processes and reporting. • Opportunities for pathologists and other laboratory professionals to educate, engage, and collaborate with clinical colleagues and interprofessional organizations to reconsider and rigorously validate algorithms for test result reporting that disproportionately impact diverse marginalized groups. • Test result reporting in an educationally, culturally, and linguistically appropriate manner.

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November 6-7, 2019	Laboratory Workforce	**Recommendation 1:** CLIAC recommends that CDC/HHS create a strategy to communicate broadly to the clinical laboratory community the Health Resources & Services Administration (HRSA) Health Careers and Opportunity Program (HCOP) resources currently available.
November 6-7, 2019	Laboratory Workforce	**Recommendation 2:** CLIAC recommends that our agency partners collaborate with relevant organizations (e.g., accrediting organizations, manufacturers, professional societies, and academic institutions for higher education bodies) to increase awareness of freely available CDC laboratory training resources.
November 6-7, 2019	Laboratory Workforce	**Recommendation 3:** CLIAC recommends that CDC create an online library of clinical laboratory educational resources for use by organizations for their own post-baccalaureate training of clinical laboratory professionals.
November 6-7, 2019	Laboratory Workforce	**Recommendation 4**: CLIAC recommends that CDC explore how virtual reality and simulation-based training can be used to achieve competency-based outcomes.
November 6-7, 2019	Remote Selection, Interpretation, and Reporting of Patient Results	CLIAC recommends that the CLIA Program consider that when laboratory professionals are providing patient care through the selection, interpretation, and reporting of patient results by accessing data remotely in a secure environment, they shall be deemed as performing those services at the primary site that houses the CLIA Certificate.
April 10-11, 2019	Personnel Requirements	The Committee deliberated, voted, and approved the following recommendations (1-12) based on the CLIA Personnel Regulations Workgroup report. CLIAC recommends that HHS consider modifying CLIA personnel requirements as follows: **Recommendation 1:** Biological science degrees such as biology, chemistry, medical technology, and clinical/medical laboratory science are acceptable degrees for laboratory personnel. Other degrees (such as those in the humanities, physical sciences, and others) may not have the requisite science coursework, and candidates for positions should be considered based on a minimum number of hours of courses with laboratory components with relevance to clinical laboratory testing (which could also come from post-degree curricular work).
April 10-11, 2019	Personnel Requirements	**Recommendation 2:** The degree in physical science should be removed from the CLIA regulations because it is too broad and may not include relevant laboratory science coursework.

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<tr><th>MEETING DATE</th><th>CATEGORY</th><th>CLIAC RECOMMENDATION</th></tr>
<tr><td>April 10-11, 2019</td><td>Personnel Requirements</td><td>Recommendation 3: All personnel should have training and experience in their areas of responsibility as listed in CLIA for their appropriate test complexity as shown in the table below.
<table>
<tr><th>CLIA Section</th><th>Role</th><th>Complexity</th></tr>
<tr><td>493.1407(e)</td><td>Laboratory director</td><td>Moderate</td></tr>
<tr><td>493.1413(b)</td><td>Technical consultant</td><td>Moderate</td></tr>
<tr><td>493.1425(b)</td><td>Testing personnel</td><td>Moderate</td></tr>
<tr><td>493.1445(e)</td><td>Laboratory director</td><td>High</td></tr>
<tr><td>493.1451(b)</td><td>Technical supervisor</td><td>High</td></tr>
<tr><td>493.1495(b)</td><td>Testing personnel</td><td>High</td></tr>
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<tr><td>April 10-11, 2019</td><td>Personnel Requirements</td><td>Recommendation 4: Remove the statement “possess qualifications that are equivalent to those required for such certification” from relevant sections noted below.
<table>
<tr><th>CLIA Section</th><th>Role</th><th>Complexity</th><th>CLIA Section</th><th>Role</th><th>Complexity</th></tr>
<tr><td>493.1405(b)(1)(ii)</td><td>Director</td><td>Moderate</td><td>493.1449(h)(1)(ii)</td><td>Technical Supervisor</td><td>High (Diagnostic Immunology)</td></tr>
<tr><td>493.1411(b)(1)(ii)</td><td>Technical Consultant</td><td>Moderate</td><td>493.1449(i)(1)(ii)</td><td>Technical Supervisor</td><td>High (Chemistry)</td></tr>
<tr><td>493.1443(b)(1)(ii)</td><td>Director</td><td>High</td><td>493.1449(j)(1)(ii)</td><td>Technical Supervisor</td><td>High (Hematology)</td></tr>
<tr><td>493.1443(b)(6)</td><td>Director</td><td>High (Oral Pathology)</td><td>493.1449(k)(1)(ii)(A) & (B)</td><td>Technical Supervisor</td><td>High (Cytology)</td></tr>
<tr><td>493.1449(b)(2)</td><td>Technical Supervisor</td><td>High</td><td>493.1449(l)(1)(i)(B)</td><td>Technical Supervisor</td><td>High (Histopathology)</td></tr>
<tr><td>493.1449(c)(1)(ii)</td><td>Technical Supervisor</td><td>High (Bacteriology)</td><td>493.1449(l)(2)(i)(B)(1), (2) & (3)</td><td>Technical Supervisor</td><td>High (Dermatopathology)</td></tr>
<tr><td>493.1449(d)(1)(ii)</td><td>Technical Supervisor</td><td>High (Mycobacteriology)</td><td>493.1449(l)(3)(i)(B)(1) & (2)</td><td>Technical Supervisor</td><td>High (Ophthalmic Pathology)</td></tr>
<tr><td>493.1449(e)(1)(ii)</td><td>Technical Supervisor</td><td>High (Mycology)</td><td>493.1449(m)(1)(ii) & (2)</td><td>Technical Supervisor</td><td>High (Oral Pathology)</td></tr>
<tr><td>493.1449(f)(1)(ii)</td><td>Technical Supervisor</td><td>High (Parasitology)</td><td>493.1449(n)(1)(ii)</td><td>Technical Supervisor</td><td>High (Radiobioassay)</td></tr>
<tr><td>493.1449(g)(1)(ii)</td><td>Technical Supervisor</td><td>High (Virology)</td><td>493.1449(q)(1)(ii)</td><td>Technical Supervisor</td><td>High (Immunohematology)</td></tr>
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Pre 2/2/1992 specifications
<table>
<tr><th>CLIA Section</th><th>Role</th><th>Complexity</th></tr>
<tr><td>493.1406(b)(1)</td><td>Director</td><td>Moderate</td></tr>
<tr><td>493.1406(b)(2)(iii)</td><td>Director</td><td>Moderate</td></tr>
<tr><td>493.1406(b)(3)</td><td>Director</td><td>Moderate</td></tr>
</table></td></tr>
<tr><td>April 10-11, 2019</td><td>Personnel Requirements</td><td>Recommendation 5: Throughout section 493, subpart M, specify that the laboratory experience described under the experience route should be “clinical laboratory experience.”</td></tr>
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April 10-11, 2019	Personnel Requirements	**Recommendation 6:** Regarding board certification, current and future HHS approved doctoral boards should be reviewed to ensure that they include a clinical component that addresses laboratory management and administration. (Current approved boards may be found at https://www.cms.gov/regulations-and-guidance/legislation/clia/certification_boards_laboratory_directors.html.)
April 10-11, 2019	Personnel Requirements	**Recommendation 7:** As a prior education requirement, 20 CME or CE credit hours specifically addressing laboratory practice commensurate with laboratory director responsibilities (CFR493.1405 and 1443) should be required for both moderate and high complexity laboratory directors except those certified by the American Board of Pathology, the American Board of Osteopathic Pathology, the American Board of Dermatology, or other boards approved by HHS.
April 10-11, 2019	Personnel Requirements	**Recommendation 8:** Regarding residency education, clarify 493.1443(b)(2)(i) by emphasizing that the requisite laboratory training must be "clinical" laboratory training: "have at least one year of clinical laboratory training during medical residency or fellowship…"
April 10-11, 2019	Personnel Requirements	**Recommendation 9:** Laboratory directors should make at least two (reasonably spaced) on-site visits to each laboratory they direct per year. On-site visits are not meant to substitute for execution of director responsibilities and are meant to supplement regular interactions between off-site directors and the laboratory (e.g., by telephone or other telepresence).
April 10-11, 2019	Personnel Requirements	**Recommendation 10:** Clear documentation of laboratory director on-site visits should demonstrate that the laboratory is in continuous compliance with current laws and regulations including but not limited to the assessment of the physical environment for safe laboratory testing.
April 10-11, 2019	Personnel Requirements	**Recommendation 11:** Consider modifying CLIA requirements for technical consultants at 493.1411 (b)(4)(i-ii) to add the option that individuals with an associate degree in chemical, biologic, or medical technology and two years of laboratory training and experience would qualify as a technical consultant.
April 10-11, 2019	Personnel Requirements	**Recommendation 12:** Consider modifying CLIA requirements for provider-performed microscopy procedures to add certified registered nurse anesthetist (CRNA) and clinical nurse specialist (CNS) to the definition of mid-level practitioner.
April 10-11, 2019	Nontraditional Testing Workflow Models	The Committee deliberated, voted, and approved the following recommendations (1-3) based on the Nontraditional Testing Workflow Model Workgroup report. The rise of big data and machine learning has led to geographically decentralized information flows and the necessity for extensive and novel controls (samples/data with known results). In response to these trends, CLIAC recommends that: **Recommendation 1:** HHS issue proposed regulations that reflect that the word "materials" in the CLIA-88 definition of a clinical laboratory shall include all data derived from a patient specimen, including images, genetic and protein sequence(s), –omics data, and other data.

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April 10-11, 2019	Nontraditional Testing Workflow Models	**Recommendation 2:** Any site that performs an activity that involves such data (provided that the activity is related to the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of, the health of human beings) shall be considered a "laboratory," if that site is not an extension of an existing CLIA-certified laboratory.
April 10-11, 2019	Nontraditional Testing Workflow Models	**Recommendation 3**: HHS develop guidance to allow distributive proficiency testing (PT) models, including analytes that are currently subject to CLIA-required PT, to assure quality across the whole testing cycle.
April 10-11, 2019	Next Generation Sequencing	The Committee deliberated, voted, and approved the following recommendations (1-8) based on the Next Generation Sequencing Workgroup report. **Recommendation 1:** CLIAC recommends that HHS thoroughly update the CLIA regulations to address issues related to new biomarker testing and other new technologies. This update may include a new section, revising existing sections, or other alternatives. This update should take account of the reports by the Personnel Regulations, Non-Traditional Workflow Models, and NGS workgroups presented to CLIAC. For NGS, such issues include but are not limited to, e.g., the definition, role, and responsibilities of bioinformaticists; quality control, e.g. moving from a simple requirement for positive and negative controls to controls more appropriate for NGS; establishment and verification of performance specifications, including the availability and sharing of samples; proficiency testing; reporting; delivery of data to patients, e.g. FASTQ vs. BAM vs. VCF-formatted NGS files; measurement, e.g. of NGS testing volumes; and data sharing, e.g. repositories and incentives and/or requirements for contribution to them.
April 10-11, 2019	Next Generation Sequencing	**Recommendation 2:** CLIAC recommends creation of a new CLIAC workgroup with the charge of advising on how CLIA might specifically be updated, integrating and reflecting the reports by the Personnel Regulations, Non-Traditional Workflow Models, and NGS workgroups presented to CLIAC, ideally incorporating members from each of these groups (for continuity).
April 10-11, 2019	Next Generation Sequencing	**Recommendation 3:** CLIAC recommends that CMS, CDC, and FDA encourage professional societies and others (e.g., CLSI) to develop and/or update NGS guidelines. Specific fields of interest include, but are not limited to, oncology, inherited conditions, and microbiology applications of NGS. Recommended topics for guidelines include but are not limited to: A) Revalidation of (i) analytical targets (e.g., additional genes or additional variant types); (ii) The bioinformatics pipeline (e.g., sequencing software updates, updates/changes in software in pipeline etc.) B) Data retention (e.g., file types, duration, intent) C) Data sharing (e.g., to patients, between organizations, between providers)
April 10-11, 2019	Next Generation Sequencing	**Recommendation 4:** CLIAC recommends that CMS, CDC, and FDA create guidelines or best practices related to clinical and public health NGS. These could be based on or in partnership with guidelines already established by the government, professional societies, or other groups (e.g., CLSI).

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April 10-11, 2019	Next Generation Sequencing	**Recommendation 5:** CLIAC recommends HHS support the incorporation of standards for interoperability and data usage in clinical genetic and genomic testing and NGS across the laboratory subspecialties.
April 10-11, 2019	Next Generation Sequencing	**Recommendation 6:** CLIAC recommends expanding the CDC GeT-RM program with regard to scope and type (e.g., wet samples and data files). Focus should be on the three major categories of oncology, inherited conditions, and microbiological applications. Expansion could also include the creation/curation of NGS data sets to be used by laboratories while validating/revalidating bioinformatic pipelines.
April 10-11, 2019	Next Generation Sequencing	**Recommendation 7:** CLIAC recommends CDC create and send a survey to laboratories and other organizations that perform NGS to collect data on bioinformaticians. Specifically, this survey should collect job descriptions and educational and training requirements, as well as the availability, hiring, roles, responsibilities, salaries, and turnover of individuals who work in roles related to bioinformatics. This survey would support the CLIAC workgroup responsible for creating suggestions about personnel changes to CLIA.
April 10-11, 2019	Next Generation Sequencing	**Recommendation 8:** CLIAC recommends that CDC carry out a survey of clinical laboratories to define the specific use cases for long-term storage (i.e., beyond diagnosis delivery) of NGS data, and for keeping archival software (including versioning), hardware (including e.g., tapes, drives, or disks), and environment/platform, to be able to re-run data under original settings.
November 7-8, 2018	Improving Diagnoses	CLIAC requests the active participation of laboratory medicine in the workings of the Federal Interagency Workgroup on Improving Diagnostic Safety and Quality. Diagnostic errors related to the total testing process lead to over 50,000 deaths each year. Inspired by the success of the CMS' role in antimicrobial resistance stewardship, CLIAC recommends that healthcare centers be required (for example by CMS, or as suggested by the Federal Interagency Workgroup on Improving Diagnostic Safety and Quality) to have an independent multidisciplinary diagnostic improvement program that includes laboratory professionals as co-equal stakeholders. The program should focus on the total testing process (including but not limited to the traditional pre-analytical, analytical, and post-analytical steps) and emphasize the cognitive elements of test selection and ordering, results in interpretation, and communication (both to the care team and patients), to promote safety, improve patient outcomes, and decrease diagnostic errors.

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November 7-8, 2018	Improving Diagnoses	CLIAC recommends that the Federal Interagency Workgroup on Improving Diagnostic Safety and Quality develop and/or centralize, with an emphasis on the cognitive processes surrounding test ordering, interpretation, and communication and the actions taken as a result thereof: • High-yield approaches to monitoring for diagnostic error • Effective best practices and research priorities for reducing diagnostic error • High-impact information-management processes related to decision support for improving diagnostic performance • Recommendations for incentivizing diagnostic performance improvement • Develop resources for improving diagnostic performance analogous to those developed for antibiotic stewardship (including through communicating with e.g., the National Quality Forum) Quantify the "total value" of laboratory diagnostics (including delineating the stakeholders, what budgets, and what units other than dollars, e.g., quality-adjusted life years, are saved or expended based on correct or incorrect decisions involving the total laboratory process).
November 7-8, 2018	Personnel Requirements	CLIAC recommends the formation of a working group to advise the Committee on how to respond to the personnel questions asked by CMS. In particular, the working group should address: (1) the educational requirements necessary for laboratory personnel, including possible use of competency exams/other key performance indicators, and leveraging the cumulative experience of existing accreditation bodies; and (2) the following issues related to requirements for clinical laboratory directors, supervisory positions, and technical consultants: supervisory experience for laboratory directors and technical supervisors, documentation/verification of training, experience, and supervisory activities, qualifications "equivalent to board certification," continuing medical education requirements as a function of degree, on-site requirements, and other clinical laboratory experience. CLIAC further recommends that CMS report to the workgroup and to CLIAC as to the breakdown of specific deficiencies related to laboratory directors, to assist the Committee in providing advice regarding the role/qualifications of laboratory directors.

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November 7-8, 2018	Role of the Laboratory in the Opioid Crisis	CLIAC recommends that the CDC, CMS, and FDA convene a blue-ribbon panel (e.g., with input from the Council for State and Territorial Epidemiologists) on laboratory engagement in controlling the opioid crisis. The panel should address the following, with emphasis on standardization of scope of testing (list of analytes), different methodologies, lack of clear reference laboratory system, inadequate capacity (especially in the forensic area), and inadequate capability to test for novel analogs (" designer opioids"): 1. How can information on the clinical and analytic properties of presumptive and definitive (confirmatory) drug testing methods be best communicated with providers who order and utilize these tests? 2. How can a list of analytes (drugs or metabolites) be standardized (e.g., nationally vs. by region), especially given the rapid change in usage patterns? 3. What incentives and regulatory approaches may improve access to definitive (confirmatory) drug testing? 4. What approaches to laboratory-based surveillance and reporting, leveraging preexisting systems for reporting public health concerns of communicable diseases, cancer, heavy metals, and HIV/AIDS (e.g., Electronic Clinical Laboratory Reporting System, New York Department of Health), might improve our ability to monitor and address the epidemic of drug misuse? 5. Investigate the feasibility for Departments of Health to require clinical laboratories to report drugs-of-abuse toxicology results (a reference laboratory system).
November 7-8, 2018	Antibiotic Resistance	In support of antibiotic stewardship efforts by the president's advisory council and others, CLIAC recommends that CMS require that clinical laboratories, in a timely fashion (e.g., within at most one year) and using reasonable effort, convert to contemporary antimicrobial resistance breakpoints in accordance with manufacturer's instructions.
November 7-8, 2018	Antibiotic Resistance	Recognizing the urgency imposed by the pace of emerging antimicrobial resistance, CLIAC recommends that the FDA update existing guidance to prioritize manufacturers' timely integration of updated antimicrobial susceptibility breakpoints.
April 10-11, 2018	Nontraditional Testing	CLIAC recommends the development of a workgroup to address non-traditional testing models. The workgroup will provide input to CLIAC for consideration in making recommendations to HHS regarding the need for optimal oversight by CLIA and best methods for such oversight in non-traditional testing models such as: • Telemedicine (i.e., remote review/interpretation/reporting of laboratory results, pathology, etc.) • Bioinformatics facilities (ex. Cloud-based programming) • NGS testing, sequencing • Toxicology

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April 10-11, 2018	Next Generation Sequencing	CLIAC recommends the formation of a next-generation sequencing workgroup to provide input to CLIAC for consideration in developing recommendations to CDC, CMS, and FDA and to prioritize regulatory gaps for assuring the quality of next generation sequencing in clinical laboratory settings. Proposed Workgroup Tasks: • Identify challenges in applying the existing regulatory framework • Identify challenges and gaps in guidance • Consider and suggest strategies to address the identified gaps and challenges • Consider and suggest strategies for assuring workforce competency
April 10-11, 2018	Laboratory Workforce	CLIAC recommends that CDC, CMS, and FDA prioritize approaches to address the 20-year shortfall of trained laboratory professionals and report back to CLIAC, including but not limited to: • Create incentives for clinical affiliate sites to allow more mentoring and training of laboratory students (similar to the Graduate Medical Education model). • Develop a crosswalk for trained veterans to accelerate entry into the laboratory professional field and qualify under CLIA regulations. • Create or evaluate existing career-ladder models developed by laboratory organizations and develop strategies to implement them. • Develop methods to demonstrate the economic impact of laboratory testing, possibly using return on investment (ROI) and/or cost-savings and avoidance. • Create strategies for increasing public awareness of clinical laboratory science as a career.
April 10-11, 2018	Laboratory Workforce	CLIAC recommends that HHS: • Issue a recommendation to the U.S. Department of Education to include laboratory science professions in science, technology, engineering, and mathematics programming. • Issue a recommendation to request that the Health Resources and Services Administration include Title VII funding to authorize resources to educational programs for laboratory professions experiencing a workforce shortage crisis. • Create a plan and appropriate funding for a program within the Public Health Service Act to ensure training for citizens seeking to enter the clinical laboratory workforce.

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April 10-11, 2018	Laboratory Workforce	CLIAC strongly recommends that HHS and/or its agencies fund a study of the opportunity costs of the two decades of reduction in the laboratory workforce. We suggest proceeding along the lines of past government funded/sponsored/written reports, such as the number of deaths due to medical errors, to provide data, context, and guidance to the public and the healthcare establishment regarding the likely effect of continued pressure on the laboratory workforce (in terms of numbers, training, and compensation). We specifically recommend: 1) a careful analysis of the role of technology and other efficiencies (perhaps reminiscent of changes to the U.S. agriculture workforce over the past century) vs. contraction of purview and provision of care (for example, resources insufficient to provide the best test with the best turnaround time, or to make improvements that would otherwise have been possible to the full laboratory cycle, as opposed to just the pre-to-post-analytical phases). 2) calculations and analysis of the ROI on laboratory personnel, in useful units (e.g., dollars, quality-adjusted life years, or errors avoided) that can be used as a landmark reference for the public, healthcare industry, and potential future members of the laboratory workforce. 3) that HHS create a workgroup or fund the process to develop a simple, quantitative method, considering current laboratory methodologies and utilization patterns, that any clinical laboratory can use to demonstrate the impact of the laboratory on the healthcare system. This method needs to be able to demonstrate the economic impact of laboratory testing, possibly using ROI and/or cost-savings and avoidance. It should also address the impact on quality of care and timeliness of results.
April 10-11, 2018	Laboratory Interoperability	CLIAC recommends that FDA and CMS create and implement guidelines for in vitro diagnostic device and laboratory information system manufacturers which describe specifications for interoperability and require the use of emerging standards such as Laboratory Analytical Workflow Profile and Logical Observation Identifiers Names and Codes for In Vitro Diagnostics.

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April 10-11, 2018	Laboratory Interoperability	The Committee recommends that the CDC consult with the Office of the National Coordinator for Health Information Technology to identify the appropriate agency to develop a report to: 1. Quantitatively define "interoperability" at each of the following levels: device, department, institution, health-care system, and nationally (e.g., "the U.S. is 12% interoperable"). 2. Determine the yearly dollar spending on interoperability, and who pays for it (manufacturers, hospitals, insurers). 3. Determine the costs in terms of adverse outcomes of a lack of interoperability, which is presumably related to the appreciable cost of diagnostic error. 4. Determine the return-on-investment for achieving (degrees of) interoperability, e.g., how much in terms of health, lives, and/or money is saved by a device/department/institution/system/the country achieving a certain level of interoperability. 5. Delineate the barriers to achieving interoperability (in terms of regulation, financial resources, human capital, conflicting values/incentives among stakeholders, access to data, and adoption).
November 1-2, 2017	Pathologist as an Integral Team Member	<u>Pathologist as an Integral Team Member</u> HHS should encourage the development and evaluation of team-based care innovations that include CLIA covered specialties (and engage patients) in reducing diagnostic error. • Areas of special interest could include consultations by laboratory professionals, e.g. pathologists' work in advising ordering clinicians on the selection, use, and interpretation of diagnostic testing for specific patients. • Evaluation should include patient and provider outcomes (including satisfaction), and health system outcomes (e.g., costs) including innovation's implementation related challenges and opportunities.
November 1-2, 2017	Laboratory Interoperability	<u>Interoperability</u> CLIAC recommends that HHS create a process for standards utilization field studies across a wide range of clinical laboratories (varying size and complexity) to: 1. Better understand the nuances, specificity, and compatibility of sharing LOINC or other standard codes, a. on both order-and result-side implementation, and b. in special cases (radiology, clinical findings, anatomic pathology, molecular diagnostics, etc.). 2. Identify areas in which a combination(s) of standards is needed to realize the level of granularity and semantic interoperability necessary to achieve the Institute of Medicine (IOM) goals.

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November 1-2, 2017	Culture-Independent Diagnostic Tests	In clinical microbiology, culture-independent diagnostic tests (CIDTs) are rapidly supplanting culture-based tests, but cultures are indispensable for surveillance and outbreak prevention, which are both cost-effective and vital to public health and national security. CLIAC recommends that CDC urgently convene a cross-agency coordinating group to assess the impact of CIDTs on public health surveillance, and to recommend impactful solutions that are brought to the attention of agency and government leaders.
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.
November 2-3, 2016	Autopsy	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.

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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. – A similar project was the CDC's *Core Elements of Hospital Antibiotic Stewardship Programs.* *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 c and diagnostic healthcare 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. Additional guidance could be obtained from the report in Recommendation 1a.
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.
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)

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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 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 the implementation of good clinical practices that also addresses transparent evaluation and monitoring of biosafety practices.
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.
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.

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November 18-19, 2015	Electronic Health Record (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 the 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.
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.
April 15-16, 2015	Electronic Health Record (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, and other relevant professional organizations • Proposes a framework for achieving safe and 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.

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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 an organ transplant. b. Appropriate criteria and decision algorithms, based on CLIAC deliberation of the Virtual Crossmatch Workgroup input, 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.
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.
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.
August 21-22, 2013	Cytology	Clinical Laboratory Improvement Advisory Committee (CLIAC) endorses the use of the College of American Pathologists (CAP) Guidelines as a model for validation of whole slide imaging systems for clinical use.

MEETING DATE	CATEGORY	CLIAC RECOMMENDATION
August 29-30, 2012	Electronic Health Record (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 catalog 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.
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.
August 31-September 1, 2011	Miscellaneous	Implement a workgroup to outline the scope of issues related to communication of laboratory testing information and propose approaches to address these issues for discussion by CLIAC.
September 1-2, 2010	Cytology	CMS should analyze the cytology proficiency testing (PT) 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.

MEETING DATE	CATEGORY	CLIAC RECOMMENDATION
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 the 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 the 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.
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.
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.
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.
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.

MEETING DATE	CATEGORY	CLIAC RECOMMENDATION
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.
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.
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 a sufficient number of participants, but the consensus is not reached.
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.
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.
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.
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.
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.
September 1-2, 2010	Proficiency Testing	Microbiology PT – 14. PT results for Gram stains should include both stain reaction and morphology.
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).

MEETING DATE	CATEGORY	CLIAC RECOMMENDATION
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.
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.
September 1-2, 2010	Proficiency Testing	Microbiology PT – 18. PT for direct antigen testing should be required for all subspecialties.
September 1-2, 2010	Proficiency Testing	Microbiology PT – 19. Retain the five required challenges per event and 80% required consensus for grading.
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.
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.
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.
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.
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.
February 9-10, 2010	Genetic Testing	Accept the Biochemical Genetic Testing (BGT) Workgroup report with changes as discussed and approved by the Committee.

MEETING DATE	CATEGORY	CLIAC RECOMMENDATION
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 the National Institutes of Health (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.
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 the 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.
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.
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.
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).
September 11-12, 2008	Genetic Testing	Form a workgroup to consider good laboratory practices for biochemical, genetic testing (BGT).
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).*
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.
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.
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.
September 7-8, 2005	Miscellaneous	Create a laboratory companion document to accompany the Clinical and Laboratory Standards Institute (CLSI) document currently under development for manufacturers addressing validation of risk mitigation.
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.

MEETING DATE	CATEGORY	CLIAC RECOMMENDATION
February 16-17, 2005	Waived Testing	Provide recommendations for good laboratory practices for waived testing.
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.
September 22-23, 2004	Miscellaneous	Send letter written by Chair, on behalf of the Committee, to CMS supporting continuing the CMS Certificate of Waiver (COW) surveys beyond 2004.
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*.
February 11-12, 2004	Waived Testing	Based on CLIAC Waiver Workgroup Report, the Committee provided recommendations for the development of criteria and oversight guidelines for waived testing to FDA and shared these recommendations with AdvaMed.
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.
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.
January 30-31, 2002	Miscellaneous	In response to CAP request, consider a letter to Secretary, HHS, regarding the 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.
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.
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.
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.
January 30-31, 2002	Miscellaneous	Send a letter to Secretary, HHS, expressing CLIAC's support of the National Laboratory System.
May 30-31, 2001	Waived Testing	Develop statement reflecting concerns about waiver of rapid, human immunodeficiency virus tests.

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February 7-8, 2001 and May 30-31, 2001	Waived Testing	Provide comments to FDA on the Draft Waiver Guidance.
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.
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.
September 27-28, 2000	Waived Testing	Send a letter to Secretary, HHS, requesting an opportunity to provide comments on waiver process and recommend FDA follow the guidelines for waiver approval published in the September 1995 proposed rule.
April 5-6, 2000	Personnel	Send a letter to Secretary, HHS, regarding crisis caused by laboratory workforce shortages.
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.
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.
September 16-17, 1998	Miscellaneous	Require that embryo laboratory procedures determined to be tested be under the purview of CLIA.
August 30-31, 1995	Quality Control	Revise requirements for certain microbiology reagents to require Quality Control (QC) testing per lot rather than daily QC testing.
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.
August 30-31, 1995	Quality Control	Include verification of accuracy, precision and reportable range as minimum core requirements for method verification for all laboratories.
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.
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.
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 the development of private and state-administered glass slide PT programs.
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 a minimum, publish APT as a proposed rule soliciting public comments on the addition of the subcategory and the proposed requirements.

MEETING DATE	CATEGORY	CLIAC RECOMMENDATION
December 13-14,1993	Personnel	Include doctoral scientists who were board eligible on February 28, 1992, as personnel qualified to serve as clinical consultants.
August 12, 1993	Personnel	Do not use board certification as the standard of competency/qualification for PPM and do not accept PPM specialty subcategories.
August 12, 1993	Waived Testing	Require that all tests, including any cleared by the FDA for home use, meet the CDC proposed guidelines for a waiver.
August 12, 1993	Waived Testing	Clarify criteria for a waiver (eliminate 'risk of harm' as a criterion for a 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.
August 12, 1993	Test Categorization	Include fecal leukocyte, wet mounts of prostatic secretions, qualitative semen analysis in PPM.
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.
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 one 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.
May 26-27, 1993	Personnel	Revise general supervisor requirements to prospectively require a bachelor's degree with a one-year laboratory training component or 3 months experience in each specialty supervised.
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.
May 26-27, 1993	Personnel	Use interpretive guidelines instead of regulations to list various qualifications (including physician board certifications) in the personnel requirements.
May 26-27, 1993	Personnel	Qualify respiratory therapists to serve as blood gas general supervisors and high complexity testing personnel.
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).
May 26-27, 1993	Personnel	Qualify neurologists with specialized training and board certification as technical supervisors, general supervisors and testing personnel of neuromuscular histology.
May 26-27, 1993	Personnel	Qualify individuals with doctoral, master's, bachelor's degrees and appropriate experience as technical supervisors of immunohematology.
May 26-27, 1993	Personnel	"Grandfather" individuals qualified under the March 1990 rule as technical supervisors.
May 26-27, 1993	Waived Testing	Waive Chemtrak Single Analyte Cholesterol Accumeter.

MEETING DATE	CATEGORY	CLIAC RECOMMENDATION
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.
February 17-18, 1993 and May 26-27, 1993	Test Categorization	Include examination of nasal smears for granulocytes in PPM.
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.
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.
February 17-18, 1993	Waived Testing	Do not add a rapid strep test to the list of waived tests.
February 17-18, 1993	Test Categorization	Do not include Gram stain, Tzanck test and rapid strep tests in PPM.
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.
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.
October 28-29, 1992	Waived Testing	Add Hemocue hemoglobin testing to the list of waived tests.
October 28-29, 1992	Test Categorization	Categorize urethral/cervical Gram stains as moderate complexity. Categorize Gram stains from all other sources as high complexity.
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.
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.