EWC 2024 Breakout Session

Open Discussion: CLIAC Committee Initiatives involving updates to CLIA regulations, Networking Clinical Labs with Public Health Labs, and More

Gregory Sossaman
MD,
Chairman, Department of Pathology and Laboratory Medicine,
Ochsner Health System,
New Orleans, LA

James Crawford
MD, PhD
Professor and Chair Emeritus,
Northwell Health
Greenvale, NY

OchsnerHealth

Clinical Laboratory Improvement Amendments of 1988 (CLIA)

- Amended section 353 of the Public Health Service Act
- Authorized Federal regulatory standards for all clinical laboratory testing performed on humans in the U.S., except clinical trials and basic research.
- Sets standards and issues certificates for clinical laboratory testing.
- Defines a clinical laboratory as any facility which performs laboratory testing on specimens derived from humans, to provide information for the diagnosis, prevention, or treatment of disease or impairment, and for the assessment of health.
- Ensure the accuracy, reliability and timeliness of test results regardless of where the test was performed.
- Centers for Medicare and Medicaid Services (CMS) has primary responsibility for the operation of the CLIA program.

CLIAC Home
Meeting
Membership
CLIAC Charter
CLIAC Workgroups
About CLIAC
CLIA
Contact CLIAC

About CLIAC

Print

The Clinical Laboratory Improvement Advisory Committee (CLIAC), managed by the Centers for Disease Control and Prevention (CDC), provides scientific and technical advice and guidance to the Department of Health and Human Services (HHS). The Committee includes diverse membership across laboratory specialties, professional roles, (laboratory management, technical, physicians, nurses) and practice settings (academic, clinical, public health), and includes a consumer representative.

The clinical and anatomic pathology laboratory specialties represented include microbiology, immunology, chemistry, hematology, immunohematology, cytopathology, histopathology, genetic testing, and informatics. The Committee also includes three ex officio members from the federal agencies that oversee the Clinical Laboratory Improvement Amendments (CLIA) program, specifically the CDC, the Centers for Medicare & Medicaid Services (CMS), and the Food and Drug Administration (FDA). Last, a nonvoting liaison representing the laboratory industry participates on the Committee.

The advice and guidance CLIAC provides to HHS pertains to general issues related to improvement in clinical laboratory quality and laboratory medicine practice. In addition, the Committee provides advice and guidance on specific questions related to possible revision of the CLIA standards.

For more information, please see the Federal Advisory Committee Database CLIAC page.

Clinical Laboratory Improvement Advisory Committee

- Established as part of CLIA 1988; membership appointed by Secretary of HHS
- Charged with providing scientific and technical advice and guidance to the Secretary of HHS regarding the need for, and nature of, revisions to the standards under which clinical laboratories are regulated; the impact of proposed revisions to the standards; and the modification of the standards to accommodate technological advances
- Will be composed of individuals involved in the provision of laboratory services, utilization of laboratory services, development of laboratory testing or methodology, and others as approved by Secretary of HHS
- Will consist of 20 members, including the chair
- Will meet twice per year

Clinical Laboratory Improvement Advisory Committee (CLIAC)

CLIAC Home
Meeting +
Membership +
CLIAC Charter
CLIAC Workgroups +
About CLIAC
CLIA
Contact CLIAC

Print

The Clinical Laboratory Improvement Advisory Committee (CLIAC), managed by the Centers for Disease Control and Prevention (CDC), provides scientific and technical advice and guidance to the Department of Health and Human Services (HHS). The Committee includes diverse membership across laboratory specialties, professional roles, (laboratory management, technical, physicians, nurses) and practice settings (academic, clinical, public health), and includes a consumer representative.

The clinical and anatomic pathology laboratory specialties represented include microbiology, immunology, chemistry, hematology, immunohematology, cytopathology, histopathology, genetic testing, and informatics. The Committee also includes three ex officio members from the federal agencies that oversee the Clinical Laboratory Improvement Amendments (CLIA) program, specifically the CDC, the Centers for Medicare & Medicaid Services (CMS), and the Food and Drug Administration (FDA). Last, a nonvoting liaison representing the laboratory industry participates on the Committee.

Get Email Updates

To receive email updates about this page, enter your email address:

Email Address

CLIA Regulations Assessment Workgroup

Print

The CLIA Regulations Assessment Workgroup provides input to CLIAC for deliberation on how the CLIA might specifically be updated, considering the April 2019 reports by the Personnel Regulations, Non-Traditional Workflow Models, and NGS workgroups. The workgroup is charged with providing advice to CLIAC for consideration in making recommendations to HHS on revising the CLIA regulations.

Co-Chairs

Kimberle C. Chapin, MD
Medical and Scientific Affairs
Cepheid

Gregory N. Sossaman, MD
System Chairman, Ochsner Health System
Department of Pathology and Laboratory Medicine
Ochsner Medical Center

Reports

- April 14, 2022 Interim Report to CLIAC
- November 9, 2022 Interim Report to CLIAC
- April 2023 Interim Report to CLIAC
- November 2023 Final Report to CLIAC

Workgroup Designated Federal Officer and Ex Officio Members

CLIA Regulatory Assessment Workgroup

Co-Chairs

Dr. Kimberle Chapin
Dr. Gregory Sossaman

Workgroup Charge

- **Established to provide** input to CLIAC for deliberation on how CLIA might specifically be updated, considering the April 2019 reports by the Personnel Regulations, Non-Traditional Workflow Models, and Next Generation Sequencing workgroups.
- **Charged with providing advice** to CLIAC for consideration in making recommendations to the Department of Health and Human Services on revising the CLIA regulations.

Kimberle C. Chapin, MD, ABMM, FCAP
Workgroup Chair

Medical and Scientific Affairs

Cepheid®
A better way.

- CLIAC member with over 30 years' experience in the clinical diagnostic arena, specifically in all areas of microbiology and molecular technologies.
- Led a diverse group of clinical laboratories that include high-complexity as well as point-of-care testing.
- Expertise in the laboratory diagnosis and clinical management of infectious disease and is actively involved in research of current molecular methods in microbiology and clinical diagnosis of microbial disease.
- Professor at Brown Medical School in Pathology and Medicine in educational and committee roles.

kim.chapin@cepheid.com
https://www.cepheid.com/

CLIAC
Clinical Laboratory Improvement Advisory Committee

Gregory N. Sossaman, MD
Workgroup Chair

System Chair of Clinical Pathology and Service Line Leader, Department of Pathology and Laboratory Medicine, Ochsner Health

gsossaman@ochsner.org
https://www.ochsner.org/

- Medical Director of multiple laboratories, including high-complexity core laboratory for Ochsner Health. Primarily practicing in clinical pathology, laboratory management, and informatics.
- Served in a variety of leadership positions and committees in organized medicine at the local, state, and national levels, such as the ASCP Board of Directors and the Louisiana State Medical Society.
- Department chair for the department of pathology and laboratory medicine at Ochsner Health, a large non-profit health system.

CLIA Regulations Assessment Workgroup

Reynolds M. Salerno, PhD
Workgroup CDC Ex Officio

Director, Division of Laboratory Systems
CLIAC Designated Federal Official

- Director of the Division of Laboratory Systems at CDC, where he oversees work to improve public health surveillance and practice and patient outcomes by advancing clinical laboratory quality and safety, data and biorepository science, and workforce competency.
- Designated Federal Official of the U.S. Clinical Laboratory Improvement Advisory Committee.
- More than 20 years of technical expertise in laboratory safety, quality, security, and risk management.
- Member of the Tri-Agency Task Force for Emergency Diagnostics and the Federal Interagency Workgroup on Improving Diagnostic Safety and Quality in Health Care.
- CDC liaison to the Board of Directors of the Association of Public Health Laboratories.

rsalerno@cdc.gov
www.cdc.gov/ophss/csels/dls/

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

CLIAC
Clinical Laboratory Improvement Advisory Committee

CLIA Regulations Assessment Workgroup

Heather Stang, MS, MT
Workgroup DFO

Deputy, Quality and Safety Systems Branch,
Division of Laboratory Systems

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

- Develops and evaluates regulatory and voluntary standards and guidelines and provides technical assistance and consultation on laboratory standards and practices
- Manages the Clinical Laboratory Improvement Advisory Committee (CLIAC)
- Co-Principal Investigator for the Next Generation Sequencing (NGS) Quality Initiative
- Over 20 years' experience as molecular biologist in academic, industry, and public health settings

hstang@cdc.gov
www.cdc.gov/ophss/csels/dls/

CLIAC
Clinical Laboratory Improvement Advisory Committee

Sarah Bennett– MT(ASCP)
Workgroup CMS Ex Officio

Technical Director,
Division of Clinical Laboratory Improvement and Quality

- Previous laboratory experience includes hospital and physician office laboratories.
- Responsible for the implementation and oversight of the CLIA laboratory program and the State laboratory regulations for the Maryland State Agency starting in 2007.
- Joined CMS, DCLIQ in January 2011, and in September 2018 became a Technical Director.

sarah.bennett1@cms.hhs.gov
http://www.cms.gov/CLIA/

Workgroup Members

- Kimberle C. Chapin, MD, ABMM, FCAP – Workgroup Co-Chair
- Gregory N. Sossaman, MD – Workgroup Co-Chair
- Tariq S. Adwan, PhD
- Erica F. Andersen, PhD, FACMG
- Jonathan B. Bakst, MBA, MHS, PA(ASCP)^{CM}
- Michael Black, MBA, MLS/DLM (ASCP)
- Qing Jackie Cao, MD, PhD
- Alexis B. Carter, MD
- David Chhieng, MD, MBA, MSHI, MSEM, MLS
- Sugganth Daniel, MD, FCAP
- Denise K. Driscoll, MS, MT(ASCP)SBB
- Birgit Funke, PhD, FACMG
- John E. Gibson MA, MT(ASCP), DLM
- William A. Glover II, PhD, D(ABMM), MT(ASCP)
- Lee Hilborne, MD, MPH, DLM(ASCP), FASCP, FCAP
- Karen Kaul, MD, PhD, FASCP
- Eric Klee, PhD
- Robert Klees, PhD
- Jordan Laser, MD, FCAP
- Christina Lockwood, PhD, DABCC, DABMGG
- Valerie Ng, MD, PhD
- Liron Pantanowitz, MD, MHA
- Elizabeth L. Palavecino, MD, FACP
- Beverly Rauch, MS
- Faiqa M. Sadique, MS, SBB, MT(ASCP), CQA(ASQ)
- Owatha “Tootie” Tatum, PhD, HCLD/CC (ABB), MBA
- Erika Tyburski
- Kevin Wickware MLS(ASCP), MBA
- Sarah Bennett, MT(ASCP) – CMS Ex Officio
- Víctor R. De Jesús, PhD – CDC Ex Officio
- Tamara Pinkney, MT(ASCP) – FDA Ex Officio
- Heather L. Stang, MS, MT(AMT) – Workgroup DFO

Out of Scope Discussions

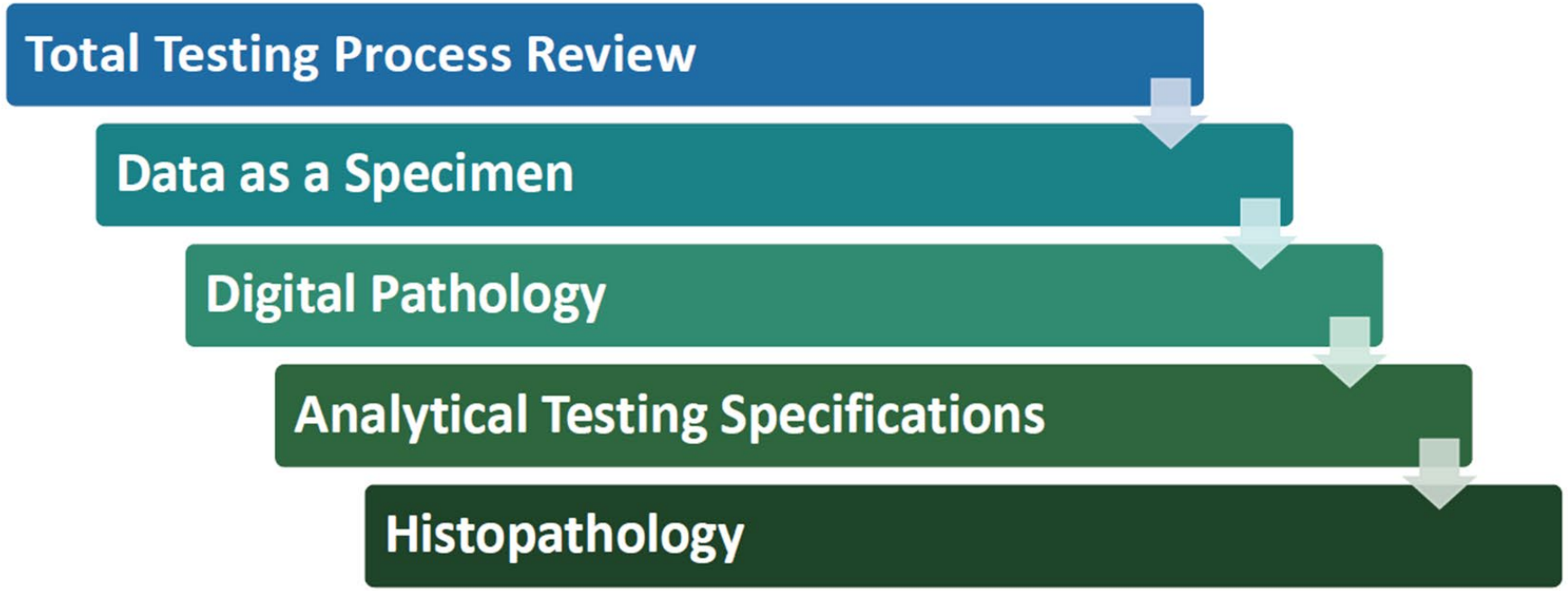
Related to the scope of the CLIA Regulations Assessment Workgroup: According to 42 CFR 493.2001, the Clinical Laboratory Improvement Advisory Committee (CLIAC) will review and make recommendations related to quality systems standards or other issues at the request of HHS. With respect to laboratory developed tests or methods developed in-house, CMS, FDA, and CDC have not requested a discussion or review of the existing CLIA regulations related to governing the development of these tests or methods, including the inclusion of performance specifications, clinical correlation, or clinical validity. Therefore, this topic is not open for discussion by CLIAC.

General Agreements

- 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.

- 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 analytical specificity. Information in the SOM should include published professional organization guidelines, as applicable.

Discussion topics



Warning!

- For the visual learners out there, this presentation will be very text heavy to capture the exact agreements and recommendations from CLIAC as documented on the website.
- Apologies beforehand for this but know there will be mostly discussion and not reading of the slides!

CLIA Regulations Assessment Workgroup Interim Report

CLIAC November 9-10, 2022

Dr. Kimberle Chapin
Dr. Gregory Sossaman

OchsnerHealth

Workgroup Agreements

- Total Testing Process
- Data as a Specimen
- New CLIA Certificate Type
- Remote Testing
- At-Home Specimen Collection
- Personnel
- Other Areas

Recommendations from CLIAC

- 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.
- 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.

Recommendations from CLIAC

- 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.
- 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.
- Recommendation 5: CLIAC recommends that FDA include, whenever possible, controls for specimen adequacy, integrity, and human origin for authorization of self-collection devices.

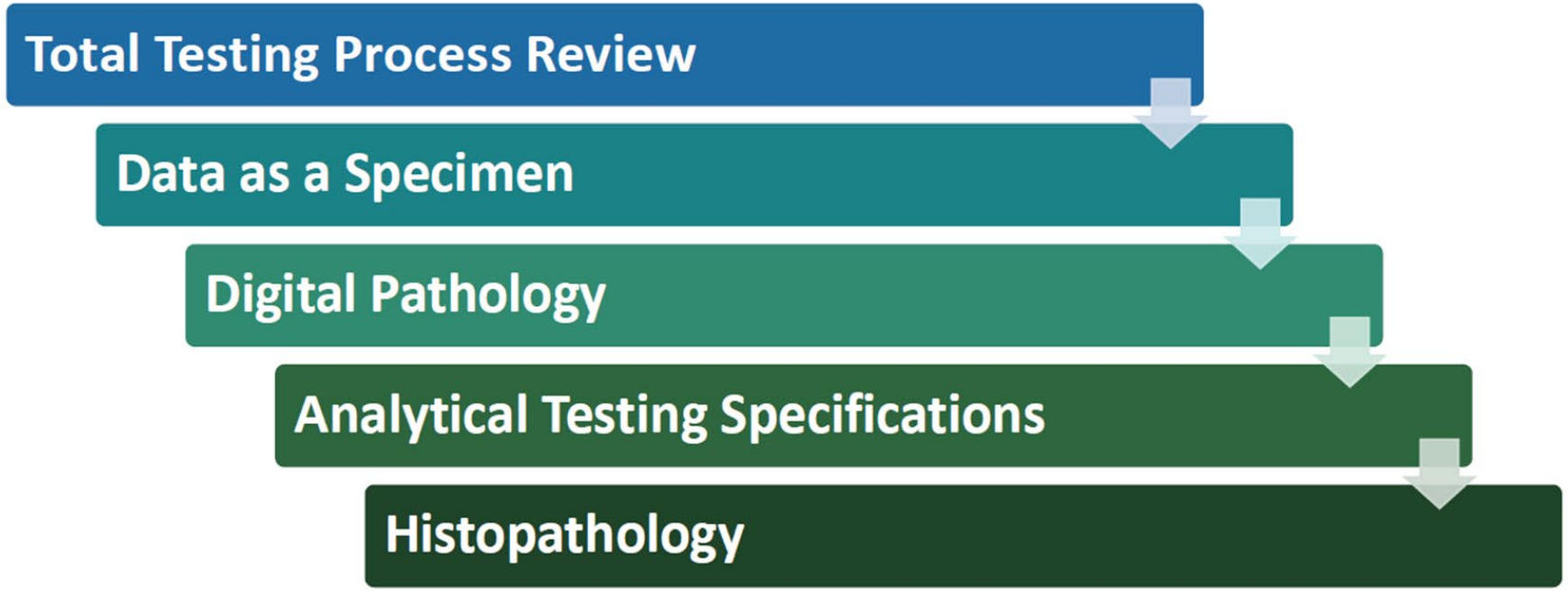
CLIA Regulations Assessment Workgroup Interim Report

CLIAC April 12-13, 2023

Dr. Kimberle Chapin
Dr. Gregory Sossaman

OchsnerHealth

Discussion topics



Workgroup Agreements

Subpart K – Quality Systems for Nonwaived Testing

Ochsner Health

§ 493.1200 Introduction

- 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.”

General Laboratory Systems

- A new standard is needed in Subpart K - Quality System for Nonwaived Testing under General Laboratory Systems related to electronic data analysis to encompass all types of electronic data that can be manipulated to generate a final laboratory test result.
- Additional information relating to the confidentiality of patient information should be included in § 493.1231 that the laboratory must follow written policies and procedures to ensure patient confidentially during data transfer to external referral laboratories, remote testing locations, or other entities. This must include cloud-based computing, such as storing confidential data, as appropriate. The laboratory must comply with other Federal laws, including the HIPAA Final Security Rule.
- The specimen identification and integrity regulations under § 493.1232 should be clarified to include a requirement that the laboratory must follow written policies and procedures for specimen acceptance and rejection to address home collection.

Preanalytic Systems

- The use of “panic or alert values” should be replaced with “a critical or clinically impactful value” at §§ 493.1241(c)(1), 493.1251(b)(11), 493.1251(b)(13), and 493.1291(g).
- The specimen labeling requirement at § 493.1242(a)(3) should be updated to remove “patient name or unique patient identifier…” and include “two unique patient identifiers…”
- Subpart K - Quality System for Nonwaived Testing, Analytic Systems must be generalized to address quantitative and qualitative test modalities.

Analytic Systems

- The CLIA regulations on analytic systems should be updated to address both qualitative and quantitative testing.
- The procedure manual requirement § 493.1251(a) should be updated to remove the reference to "Textbooks" and replace it with "Other materials reflecting current practice…"
- 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 include data collection and analysis. Examples can be added to the SOM.
- The regulations related to the reportable range at § 493.1251(b)(6) should be clarified to address both qualitative and quantitative test results. For example, § 493.1251(b)(6) should include "The reportable range for qualitative test results…" Also, § 493.1251(b) should be updated to include a new requirement for the reportable qualitative test result for the test system as established or verified in § 493.1253.

Postanalytic Systems

- The regulations related to the requirement for a test report at § 493.1291 should be clarified to include requirements for new processes, such as the distributive testing process and remote sign-out for digital pathology.
- The CLIA regulations should define “test report” to clarify if the release of information through other means, such as a patient portal, should have the same requirements as the “test report” requirements currently in CLIA.
- The regulations related to the requirement for the name and address of the laboratory location where the test was performed at § 493.1291(c)(2) should be updated to “location(s)” and clarified to allow for laboratories to use a code for testing address if performed in a home office.
- The “test report date” should be clarified at §493.1291(c)(3) to distinguish from the date all results are final or if each date that results are released is required.

CLIAC Recommendations

- 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.
- 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.
- Recommendation 3: Subpart K - Quality System for Nonwaived Testing, Analytic Systems should be generalized to address quantitative and qualitative test modalities.
- 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.”

CLIAC Recommendations

- 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.
- 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.
- 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.

CLIAC Recommendations

- Recommendation 8: CLIAC recommends that CMS include information related to specimens collected outside of the laboratory's control in the SOM.
- 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).
- 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."
- 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."
- 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.

CLIAC Recommendations

- Recommendation 13: The SOM should be updated to include a definition of interfering substances as mentioned in § 493.1251(b)(9).
- 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).
- 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.
- 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.

CLIAC Recommendations

- 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.
- 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.
- 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. Page 12 of 19
- 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.

CLIAC Recommendations

- 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.
- Recommendation 22: The SOM should be updated to include guidance for tests where two levels of quality control are not beneficial.
- 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.
- 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.

CLIAC Recommendations

- 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.”
- Recommendation 26: The regulations related to cytology at § 493.1274 should be reevaluated in recognition of the more diverse interpretive workload and practice context.
- 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

CLIAC Recommendations

- Recommendation 28: The regulations related to the requirement for test records at § 493.1283 should be updated to include patient confidentiality requirements. Page 13 of 19
- 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

CLIA Regulations Assessment Workgroup Interim Report

CLIAC April 8, 2023

Dr. Kimberle Chapin
Dr. Gregory Sossaman

OchsnerHealth

Workgroup Questions - Histopathlogy

- Are additional personnel categories needed in CLIA to address anatomic pathology testing processes?
- Should CLIA recognize the role that histotechnicians, histotechnologists, and pathology assistants play in the total testing process?
- What personnel qualifications and responsibilities should be required for histotechnicians, histotechnologists and pathology assistants?
- What is an appropriate timeframe for review and confirmation of the tissue findings by the technical supervisor after the gross tissue examination is performed by qualified high complexity testing personnel?

Workgroup Agreements

- CLIA should be updated to include personnel requirements for anatomic pathology processing.
- A CLIA personnel category for histotechnicians, histotechnologists, and pathology assistants should be created with defined educational requirements similar to those for high complexity testing personnel.
- Personnel qualifications for histotechnicians, histotechnologists, and pathology assistants should be similar to high complexity testing personnel qualifications.

CLIAC Recommendations

- Recommendation 1: CLIAC recommends that CMS update CLIA to recognize histotechnicians, histotechnologists, and pathology assistants as testing personnel and define educational requirements for each personnel category.

CLIAC Recommendations

- So, what happens next?
- Do recommendations always lead to changes in CLIA?
- How do we know when these changes will get implemented?
- Is there a process to this?
- Does CLIA actually evolve?
- Evolution, not revolution

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality

Ref: QSO-24-03-CLIA

DATE: December 28, 2023

TO: State Survey Agency Directors

FROM: Directors, Quality, Safety & Oversight Group (QSOG)

SUBJECT: Final Rule- Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees, Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories (CMS-3326-F)

Memorandum Summary

- **Publication of Final Rule: CMS-3326-F was published on December 28, 2023.** This final rule updates the Clinical Laboratory Improvement Amendments of 1988 (CLIA) fees and clarifies the CLIA fee regulations. Specifically, the final rule will: 1) implement a process for sustainable funding for the CLIA program through a biennial two-part increase of CLIA fees; 2) amend histocompatibility and personnel regulations under CLIA to address obsolete regulations and update the regulations to incorporate technological changes; and 3) amend the provisions governing alternative sanctions (including civil money penalties, a directed plan of correction, a directed portion of a plan of correction, and onsite State monitoring) to allow for the imposition of such sanctions against non-compliant laboratories operating under Certificates of Waiver, rather than being limited only to imposing principal sanctions of revocation, suspension or limitation of a laboratory's CLIA certificate.

- **Effective Dates:** These regulations are effective January 27, 2024, except for instruction 3, amending § 493.2; instructions 14 through 19, amending §§ 493.945, 493.1273, 493.1274, 493.1278, 493.1359, and 493.1405; instruction 20 removing § 493.1406; instructions 21 through 30, amending §§ 493.1407, 493.1411, 493.1417, 493.1423, 493.1443, 493.1445, 493.1449, 493.1451, 493.1455, and 493.1461; instruction 31 removing § 493.1462; and instructions 32 through 36, amending §§ 493.1463, 493.1469, 493.1483, 493.1483, 493.1489, and 493.1491, which are effective December 28, 2024.

Personnel, §§ 493.1359 through 493.1489

The CLIA regulations related to personnel requirements were updated with minor changes to the doctoral high complexity laboratory director qualifications in the 2003 final rule, but otherwise have remained unchanged since we published the 1992 final rule with comment period. In the 2018 RFI, we sought public comment and information related to CLIA personnel requirements in the following areas: nursing degrees; physical science degrees; personnel competency assessment (CA); personnel training and experience; and non-traditional degrees. As we explained in the 2018 RFI, these are areas that the CDC, CMS, interested parties, and State agency surveyors identified as relevant to our efforts to update the CLIA personnel requirements to better reflect current knowledge, changes in the academic context, and advancements in laboratory testing. We also requested input from CLIAC for recommended changes to the CLIA personnel requirements found in subpart M – Personnel for Nonwaived Testing, §§ 493.1351 through 493.1495.

CMS and CDC are finalizing the proposed updates to the CLIA regulations for Personnel, with some modifications, including:

1) Remove the proposed addition of a nursing degree qualification for high complexity testing personnel;
2) Revise the language of the regulations addressing laboratory director qualifications, to specify that an individual qualifying under the doctoral degree algorithm must have an earned doctoral degree; and

---

[2] The CLIAC managed by the CDC, established under the Federal Advisory Committee Act, provides scientific and technical advice and guidance to the Department of Health and Human Services (HHS). The Committee includes diverse membership across laboratory specialties, professional roles, (laboratory management, technical, physicians, nurses) and practice settings (academic, clinical, public health), and includes a consumer representative.

CLIA Amendments in CFR

https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493

§ 493.25 Laboratories performing tests of high complexity.

(a) A laboratory must obtain a certificate for tests of high complexity if it performs one or more tests that meet the criteria for tests of high complexity as specified in § 493.17(a).

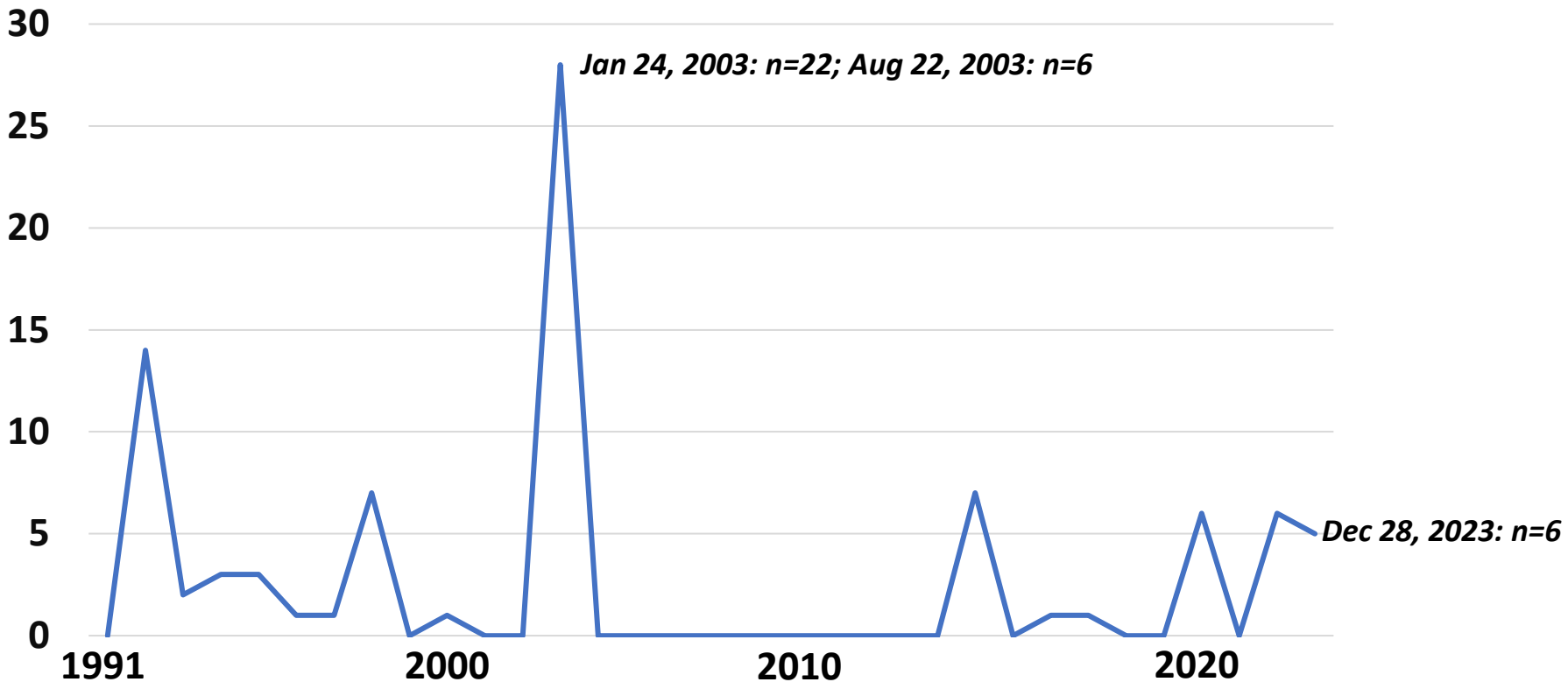
(b) A laboratory performing one or more tests of high complexity must meet the applicable requirements of subpart C or subpart D, and subparts F, H, J, K, M, and Q of this part.

(c) If the laboratory also performs tests of moderate complexity, the applicable requirements of subparts H, J, K, M, and Q of this part must be met. Under a registration certificate or certificate of compliance, PPM procedures must meet the inspection requirements at §§ 493.1773 and 493.1777.

(d) If the laboratory also performs waived tests, compliance with §§ 493.801(a) and 493.801(b)(7) and subparts J, K, and M of this part are not applicable to the waived tests. However, the laboratory must comply with the requirements in §§ 493.15(e), 493.801(b)(1) through (6), 493.1771, 493.1773, and 493.1775.

[57 FR 7139, Feb. 28, 1992, as amended at 60 FR 20044, Apr. 24, 1995; 68 FR 3702, Jan. 24, 2003; 68 FR 50723, Aug. 22, 2003; 87 FR 41232, July 11, 2022]

CLIA Amendments, as published in Federal Register



CLIA can change, but it’s a process

Questions?

Appendix

- Remaining slides are the rest of the workgroup agreements on Subpart K

CLIA Regulations Assessment Workgroup Interim Report

CLIAC November 9-10, 2022

Dr. Kimberle Chapin
Dr. Gregory Sossaman

OchsnerHealth

Workgroup Agreements

Total Testing Process

1. A laboratory's requirements under CLIA should start when a specimen arrives in the laboratory for testing.

2. A laboratory's requirements under CLIA should continue through the total testing process, including data interpretation, and reporting even when performed remotely.

Data as a Specimen

1. The CLIA definition of a laboratory includes the terminology “materials derived from the human body,” and that “derived” should apply to images and data because they are a derivation of material from the human body.
2. The term “materials” should be defined in CLIA as the patient specimen, including data derived from a patient 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.
3. The definition of a “test system” should be modified in CLIA to all of the instructions, instrumentation, equipment, reagents, supplies, software algorithms, data analysis procedures, and other components needed to perform an assay or examination and generate test results.

New CLIA Certificate Type

1. If an entity is manipulating information, performing data analysis, etc., received from a clinical laboratory and returning it to the laboratory for inclusion in the patient report or for patient care, that entity needs to have the appropriate CLIA certificate.
   - Under that CLIA certificate, they are subject to the same patient confidentiality and requirements as the referring laboratory.
2. Entities that perform informatic analysis and interpretation of laboratory data should be certified under CLIA. This may require a new type of CLIA laboratory designation beyond Certificate of Compliance or Accreditation.

Remote Testing

1. 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.
2. Under a distributive model where a laboratory performs the wet laboratory work, and another separate entity performs the data analysis and/or interpretation, those two sites should have separate and distinct CLIA certificates, and proficiency testing should be required for both locations.
3. The CLIA regulations should be revised to allow remote analysis for any CLIA specialty or subspecialty.
4. A laboratory's CLIA certificate covers the qualified laboratory personnel when using a VPN to review and report cases remotely.

At-Home Specimen Collection

The COVID-19 pandemic brought at-home specimen collection to the forefront. Laboratory testing quality begins during specimen collection, and it would be very difficult to inspect the front-end process of specimen collection, including at-home or remote, packaging, transportation, patient information validation, etc.

There should be more stringent requirements for stability studies both with the vendor and as a confirmation in the laboratory to address the specimen shipment issues.

- Vendors should perform studies (stability, transportation, etc.) on at-home collected specimens and provide that information as part of the FDA approval process. These studies should include specimen stability.
- FDA should consider requiring a human adequacy control for detection in a specimen and at-home collection and testing.
- Specimen collection devices should have internal controls to ensure sufficient specimen was collected and monitor the specimen's integrity during transportation to the testing laboratory.
- Laboratories that choose to use a home collection device that has not been cleared for use by the FDA will need to submit that device for FDA review and approval.
- Laboratories must have policies in place to accept and reject specimens collected outside of their laboratory, including home-collected specimens. If the laboratory chooses to test a specimen that falls outside of the collection device's manufacturer's instructions, then the laboratory will need to provide performance studies to validate that modification.

Personnel

1. Workgroup members agree that CLIA should broadly define new personnel roles, such as the personnel performing activities such as bioinformatic data analysis, variant classification, variant analysis for patient care, etc. (variant scientists).
2. CLIA should require training and competency assessments for staff such as pathology assistants, image technicians, cytotechnologists, and histotechnologists that are performing digital pathology and digital image analysis. This may require the establishment of a new personnel category in CLIA or additional competency requirements.
3. A new specialty is needed to accommodate the post-analytic analysis of laboratory data or results to accommodate other practice areas such as next generation sequencing (NGS), drug screen toxicology, etc.

Analytic Systems

- The CLIA regulations should be updated to include a definition of interfering substances as mentioned in § 493.1251(b)(9). Examples related to homologous genome regions can be added to the SOM.
- The use of “normal values” should be replaced with “expected result(s)” at §§ 493.1251(b)(10), 493.1253(b)(1)(ii), 493.1253(b)(2)(vi), 493.1282(b)(iii), and 493.1291(d). The term “reference intervals” does not equal “normal values” for genetic and other qualitative tests.
- The CLIA regulations under § 493.1252 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.
- The regulations related to test systems not subject to FDA clearance or approval at § 493.1253(b)(2) should be updated to include laboratory developed test terminology in addition to “in-house” methods.

Analytic Systems

- In addition to textbook procedures, § 493.1253(b)(2) should be updated to include “other material reflecting current practice.”
- 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.
- 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.
- The requirement for including at least a minimal (or zero) value, a mid-point 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.”
- The SOM should be updated to include more guidance on control procedures for multiplex cartridges related to § 493.1256.

Analytic Systems

- The CLIA regulations for control procedures under § 493.1256(d)(3)(i) should be updated to reflect tests such as next generation sequencing where two levels of quality control at different concentrations are not helpful.
- The specification for thin layer chromatography under § 493.1256(d)(4) should be removed from the CLIA regulations and included in the SOM.
- The specialty and subspecialty sections starting § 493.1261 through § 493.1278 should be updated to remove test specificity and outdated technologies. 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.

Analytic Systems

- The regulations related to hematology at § 493.1269(a)(1) should be updated to "One control material must be tested every 8 hours of operation by each individual performing tests."
- 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."
- The regulations related to cytology at § 493.1274 should be clarified to account for the use of immunocytochemical slides in workload recording.
- The regulations related to the requirement for an annual statistical laboratory evaluation for cytology at § 493.1274(c)(5) should be removed.

Analytic Systems

- The regulations related to the requirement for comparison of test results at § 493.1281(a) should be clarified to emphasize tests for the same analyte or methodology. The SOM should be updated to clarify the comparison of test results requirements described under § 493.1281. The update should include information on 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, or tests with different sensitivities.
- The regulations related to the requirement for test records at § 493.1283 should be updated to include patient confidentiality requirements.
- 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, as some assays have a very short specimen viability window.