COLA'S Summer Edition 2024

inSIGHTS

IN THIS ISSUE:

LETTER FROM THE CHAIR

SUMMER EDITION 2024

Keeping up with **regulatory changes** is important not only to ensure compliance, but also to ensure high quality laboratory test results and improved patient outcomes. For more than 35 years, **COLA** has worked to promote health and safety through accreditation and education. We work closely with our regulatory partners to understand the details of proposed and finalized changes, and use our avenues of communication and education, such as this inSights publication, to keep laboratories informed and prepared for change.

In this edition of inSights, we are sharing important information about upcoming changes to the **CLIA regulations**, including updates in the **areas of proficiency testing and personnel qualifications**. We will also discuss the **FDA Final Rule on laboratory-developed tests (LDTs)** so that laboratories know what to expect during the four-year phase-out of the FDA's enforcement discretion regarding LDT oversight, should the final rule be implemented as written. We recognize that there are efforts underway to stop the implementation and we are monitoring this situation closely.

Finally, due to the far-reaching effects of the persistent shortage of laboratory workforce in healthcare, inSights has decided to launch a new regular column that focuses on the **Workforce Action Alliance** and the progress they are making towards understanding and alleviating the strain on the laboratory workforce.

We hope that this edition helps to bring you up to speed on the latest news in laboratory science, and we welcome your feedback!

Keith Davis, MD, FAAFP
Chair, COLA Board of Directors

Race-free eGFR Equations: Adoption and Obstacles

By: Jennifer MacCormack, MLS (ASCP)^{CM}

Jennifer MacCormack is an experienced science and medical writer with a background in clinical laboratory testing, medical & health science, and regulatory oversight. She received her Bachelor of Science in Physiology from McGill University.

The estimated glomerular filtration rate (eGFR) has long been used as a means of estimating a patient's overall kidney function and to inform the diagnosis of chronic kidney disease (CKD). A patient's eGFR result can determine the course of their treatment, including whether or not they are considered for dialysis or placed on the kidney transplant list.

Historically, the algorithms used for calculating the eGFR factored four elements: age, gender, race and serum creatinine. Over the past decade, many healthcare professionals have advocated for the removal of race from the eGFR algorithm, due to evidence that including race as a factor may be leading to delays in Black patients being referred for kidney transplant. This is because when the race coefficient is used, the equation delivers a higher eGFR result for a Black patient than for a non-Black patient with the same serum creatinine level. Additionally, there is the significant problem of determining which version of the algorithm to use when patients are of mixed or unknown race.

In response to these concerns, the National Kidney Foundation (NKF) and the American Society of Nephrology (ASN) created a Task Force on Reassessing the Inclusion of Race in Diagnosing Kidney Diseases to determine whether the historical algorithm for calculating eGFR, which includes a race coefficient, may be creating inequities in health care. Their final report, published in April 2022, recommended using new calculations without a race coefficient: the 2021 CKD-EPI equation.

Adoption Survey

In November 2023, COLA distributed an optional online survey to determine how many COLA-accredited laboratories had already made the change to the race-neutral 2021 CKD-EPI eGFR equation, or were planning to. Laboratories who had not yet implemented the new calculations were also asked about their reasons why, so that we could report to the NKF and help them better understand the obstacles impeding widespread adoption.

We received responses from 89 laboratories spread across 30 states. Of the responding laboratories, approximately 50% were physician office practices. Hospital or health center laboratories represented 40% of the respondents, with the remaining laboratories identifying as either government or independent laboratories.

A majority of surveyed laboratories (58%) reported current use of the race-neutral 2021 CKD-EPI equation for eGFR. Approximately a third of respondents were still using an eGFR calculation that includes a race coefficient, either the MDRD study equation (16%) or the 2019 CKD-EPI equation (13%). Very few laboratories (3%) reported use of the Cockcroft-Gault equation, and 9% of respondents were unsure which equation was currently in use in their laboratory (see Figure 1).

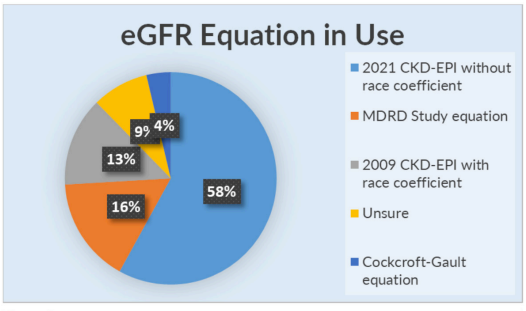

Figure 1

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Of the laboratories not yet using the new equation at the time of the survey, 73% had plans for implementation by the end of 2024. Of the laboratories with no concrete plans to implement the new equation, some cited software limitations and the need to coordinate logistics with the facility's information technology department. Some laboratories reported slow management approval processes or needing to wait until the parent health system implemented the change. Other reasons given included a limited or unique patient population, low test volume, and disagreement with the conclusions of the Task Force report (see Figure 2).

The results we collected with this survey correlate closely with the responses collected in similar surveys conducted by the NKF and other accreditation organizations. A majority of U.S. laboratories have either already made the change to a race-neutral assessment of eGFR or have plans to do so by the end of this year. While adoption is still far from universal, a better understanding of the obstacles will help the NKF and other groups to develop educational materials and guidance for laboratory professionals to facilitate the transition.

For more information on the new eGFR calculations and guidelines for implementing the changes in your laboratory, please see the National Kidney Foundation's Recommendations for Implementing the CKD-EPI 2021 Race-Free eGFR Calculation: Guidelines for Clinical Laboratories.

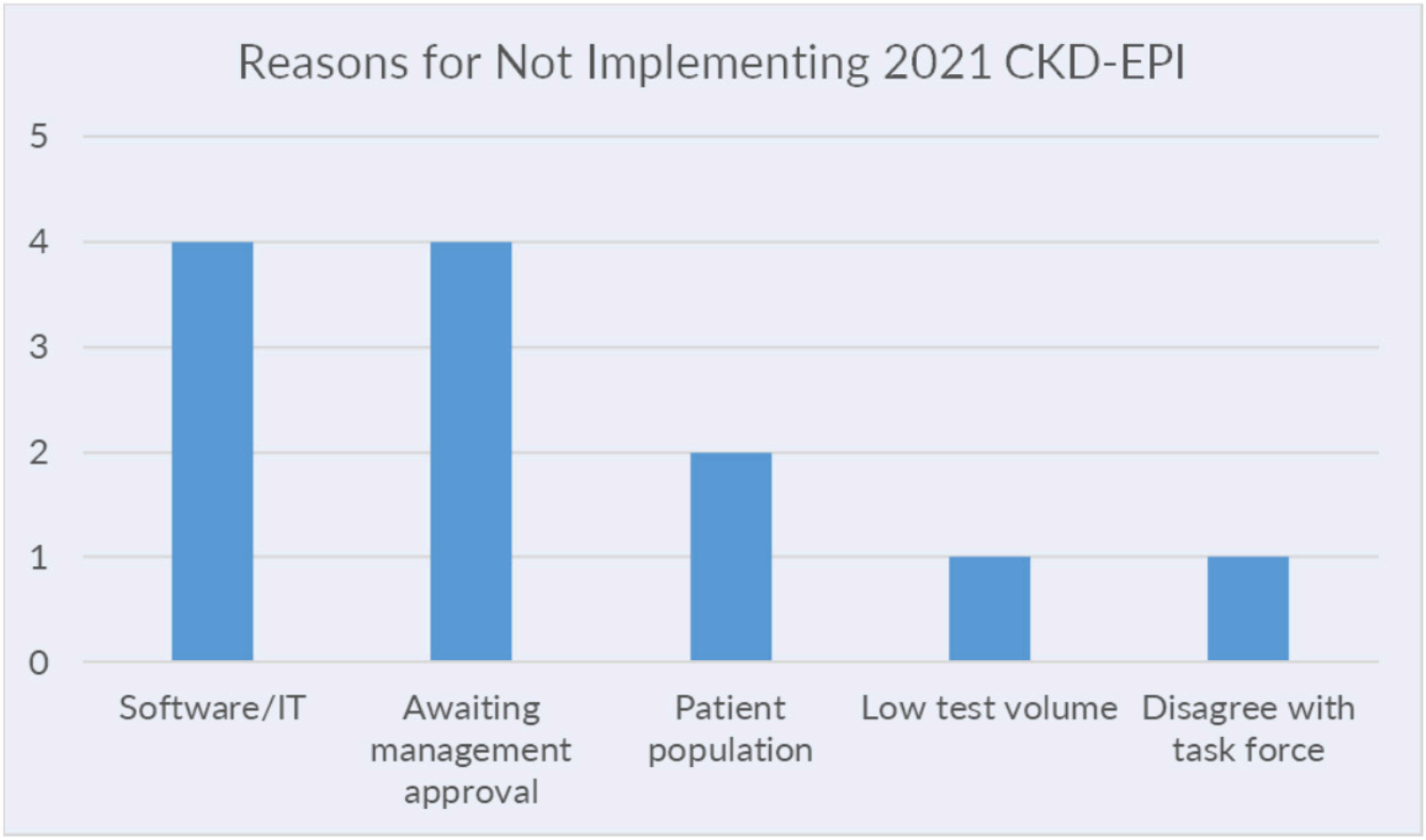

Figure 2

Additional Resources:

Task force report: https://academic.oup.com/clinchem/article/68/4/511/6463626

NKF guidance on implementation: https://www.kidney.org/content/national-kidney-foundation-laboratory-engagement-working-group-recommendations-implementing

NKF eGFR calculator: https://www.kidney.org/professionals/KDOQI/gfr_calculator

A New Framework:
Unpacking the FDA's Comprehensive Overhaul of LDT Regulations

By: David Chhieng, MD, MBA, MSHI, MSEM, MLS, MDR

Dr. David Chhieng is the Chief Medical Officer of COLA. Before he joined COLA, he was a Professor, the Director of Anatomic Pathology and Pathology Informatics, and Vice Chair of Clinical Operation, of the Department of Pathology at the University of Washington in Seattle WA. Prior to that, he was the Director of Cytopathology at the Yale University and the Icahn School of Medicine at Mount Sinai.

Dr. Chhieng obtained his MD degree from the University of Hong Kong and completed several master degrees in Business Administration, Health Informatics Management, Engineering Management, Legal Studies and Dispute Resolution. His fellowship training in Surgical Pathology and Cytopathology at the Memorial Sloan Kettering Cancer Center and New York University, respectively. He is board certified in Anatomic and Clinical Pathology, Cytopathology, and Clinical Informatics. He has been a practicing surgical and cytopathologist for 20+ years and in a directorship position for 10+ years.

The U.S. Food and Drug Administration (FDA) has introduced a significant regulatory shift with the publication of its Final Rule on laboratory-developed tests (LDTs) in the Federal Register, effective from May 6, 2024. This rule marks the gradual end of FDA's long-standing policy of enforcement discretion related to LDTs. Historically, LDTs were not held to the strict requirements outlined for medical devices in the Federal Food, Drug, and Cosmetic Act (FD&C Act) due to this policy. Going forward, LDTs will be officially classified as regulated medical devices, initiating a structured four-year phase-out of the FDA's enforcement discretion and regulatory oversights.

Expanded Definition and Regulatory Implications:

The new rule redefines "in vitro diagnostic products" (IVDs) to explicitly include LDTs, clarifying their status under FDA oversight as medical devices. This change necessitates that during the phase out period LDTs will gradually be asked to comply with the reporting, registering, labeling, quality systems and premarket approval requirements outlined in the FD&C Act.

Phase-Out Strategy and Scope:

The FDA has outlined a detailed phase-out policy, structured in five stages over four years, to integrate LDTs into the existing regulatory framework for medical devices. This policy applies to both traditional LDTs and those developed by high-complexity, CLIA-certified laboratories. Notably, the phase-out excludes direct-to-consumer tests and those intended for emergency use or manufactured outside of a clinical laboratory setting, which must immediately comply with all relevant FDA regulations.

Key Stages of the Phase-Out:

1. Stage 1: One year after the rule's publication, FDA expects compliance with Medical Device Reporting (MDR), correction and removal reporting and Quality System (QS) requirements related to complaint files.
2. Stage 2: Starting two years post-publication, the focus shifts to requirements not addressed in Stage 1, including registration and listing, labeling and investigational use requirements.
3. Stage 3: Starting three years after publication, compliance with broader QS requirements under part 820 is expected, excluding those already implemented in Stage 1.
4. Stage 4: Starting three and a half years post-publication, FDA anticipates compliance with premarket review requirements for high-risk IVDs offered as LDTs, continuing to exercise enforcement discretion during the pendency of its review if a premarket submission is made by the start of this stage.
5. Stage 5: Beginning four years after publication, compliance with premarket review for moderate-risk and low-risk IVDs offered as LDTs is expected, with enforcement discretion continuing during the review of submissions made at the beginning of this stage.

These stages aim to ensure a smooth transition, with the FDA providing targeted guidance and additional resources throughout the phase-out period to facilitate compliance. The approach takes into account both the technical complexities of LDT regulation and the practical needs of laboratories adjusting to new regulatory expectations.

Exceptions and Grandfathering Provisions:

The October 2023 proposed rule identified three categories of tests that would remain exempt from device regulatory controls under the final rule. These include:

- "1976-type LDTs": Manual assays by specialized technicians using legally marketed components.
- Human leukocyte antigen (HLA) tests: used in the contexts of organ, stem cell and tissue transplantation.
- Tests exclusively used for forensic purposes.

The final rule expands these exceptions to

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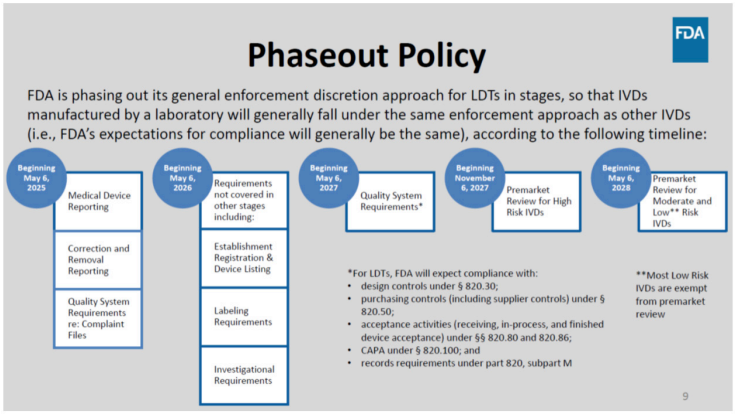
include several significant and somewhat unexpected categories of in vitro diagnostics (IVDs), reflecting the FDA's responsiveness to over 6,500 comments from stakeholders. The rule meticulously details each exception and the public health rationale behind them. Additional categories of IVDs that receive either full or partial continued enforcement discretion under the final rule include:

- LDTs produced and used within the Veterans Health Administration or Department of Defense: These remain under full enforcement discretion.
- LDTs approved under the New York State Department of Health Clinical Laboratory Evaluation Program (NYS CLEP): These include those approved, conditionally approved, or exempt from full technical documentation. For these, FDA enforcement discretion applies only to premarket review requirements, due to similar premarket review processes between the FDA and NYS CLEP. Other device general controls will still apply as per the phased-in timeline of the final rule since New York State lacks equivalent controls for the clinical laboratory industry. The FDA also plans to require labeling from laboratories producing NYS CLEP-approved tests to better assess their compliance.
- LDTs developed and used by laboratories integrated within a healthcare system: These are designed to meet an unmet medical need for patients within that system. Enforcement discretion for these tests is limited to premarket review and most quality system requirements, except for medical device records under 21 C.F.R. Part 820, Subpart M. This enforcement discretion does not apply if a patient is treated at a hospital affiliated with a laboratory under different corporate ownership, or if the ordering physician lacks staff privileges at such a hospital.
- LDTs marketed before the final rule's issuance (May 6, 2024): For these, enforcement discretion applies only to premarket review, similar to the FDA's approach to those approved under NYS CLEP. One caveat is that the enforcement discretion only applies if the tests are not significantly modified. Changes in clinical use, operational principles, technology, performance and/or safety specifications will subject the LDTs to full medical device regulations. Additionally, the FDA will require labeling from laboratories to review test performance and validation, ensuring compliance with regulations. New tests introduced post-May 6, 2024, will not benefit from this enforcement discretion, aligning them directly under the stringent oversight of medical device regulations.
- LDTs for rare red blood cell antigens: Manufactured and used in blood establishments like transfusion services and immunohematology laboratories, where no alternative testing exists to ensure blood compatibility. These tests will also receive enforcement discretion mainly in premarket review and most quality system requirements, excluding medical device records.

VALID Act and FDA Final Rule

A stark contrast exists between the FDA's approach in the Final Rule and the proposed Verifying Accurate Leading-edge IVCT Development (VALID) Act, which has not been passed by the Congress. The VALID Act suggested broad regulatory exemptions for all pre-existing LDTs. In comparison, the FDA's rule does not include such broad exemptions and takes a stricter stance on "grandfathering."



Insights from the Former Director of the FDA's Office of In Vitro Diagnostics

At this year's COLA Laboratory Enrichment Forum, Timothy Stenzel, MD, former Director of the FDA's Office of In Vitro Diagnostics, elaborated on the broad implications of the FDA's final rule on LDTs. He forecasted a surge in LDT approval applications in New York State and a busy period ahead for the FDA as it manages a high volume of Pre-Submission (Pre-Subs) and Q-Submission (Q-Subs) inquiries seeking clarifications on the new regulations. He also noted that the final rule also includes provisions for Emergency Use Authorizations and introduces two new draft guidance documents aimed at public health laboratories and those developing tests for emerging pathogens, allowing for enforcement discretion during public health emergencies.

Anticipating legal challenges to the Final Rule, Dr. Stenzel predicted potential delays in its implementation and the possibility of prompting congressional action, particularly if legal proceedings were drawn out or if courts ruled against the FDA. He also pointed out the uncertainties surrounding the impact of this rule on the proposed VALID Act, which aims to establish a new regulatory framework for IVDs, including LDTs. Stakeholders might push for the VALID Act as a more favorable alternative, given the potential legal challenges to the FDA's approach.

Final Thoughts

The FDA's Final Rule on LDTs marks a pivotal shift in regulatory practices, establishing stricter oversight and a clear compliance framework for laboratories. This change gradually phases out the broader enforcement discretion previously granted, moving towards more rigorous standards. To facilitate this transition, the FDA plans to provide additional guidance to laboratories, helping them to navigate the new requirements during this adjustment period. However, the introduction of this rule may spark legal challenges questioning the FDA's authority over LDTs, potentially shaping future regulatory approaches to laboratory testing. The contentious nature of the rule could also rekindle legislative efforts, such as the VALID Act. As these regulatory changes unfold over the next four years, the interplay between regulatory objectives, industry practices and healthcare needs will be crucial in defining the future governance of LDTs.

PostScript:

On May 29, the American Clinical Laboratory Association (ACLA) filed a lawsuit against the FDA over the new LDT rule. On June 28, in a 6–3 decision in the case Loper Bright Enterprises et al. v. Raimondo, the U.S. Supreme Court overturned Chevron deference. This decision implies that greater judicial scrutiny of agency interpretations is now expected, which could support ACLA's argument against the FDA's classification of LDTs as medical devices.

The Supreme Court ruling may also prompt Congress to reconsider the VALID Act, a bill intended to regulate LDTs less stringently than the FDA's rule. Many laboratories, including academic medical centers, might see the VALID Act as a more favorable alternative.

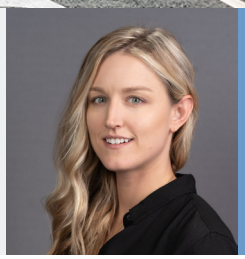
Reference:

U.S. Food & Drug Administration: Final Rule Medical Devices, LDTs, May 14, 2024; Webinar Presentation, Slide #9,; https://www.fda.gov/medical-devices/medical-devices-news-and-events/webinar-final-rule-medical-devices-labboratory-developed-tests-05142024; Last Checked 5/23/24

CMS Updates

By: Lauren Albrecht, MPH, MLS (ASCP)[CM]

Lauren Albrecht has six years of clinical laboratory experience where she spent most of that time working in the blood bank at University Hospitals in Cleveland, Ohio. She went on to receive an MPH in epidemiology at Kent State University to help supplement her Medical Laboratory Scientist certification. She has been with COLA for over seven years now working as a Surveys Team Leader after five years of surveying.



There is exciting news on the horizon: at the end of 2023, the Centers for Medicare and Medicaid Services (CMS) published a final rule including some much-needed updates to the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations. The full text of the rule addresses an update to CLIA fees, amended histocompatibility and personnel regulations and provisions governing alternative sanctions with regards to waived-only laboratories. In this article we will discuss the changes to personnel regulations that are going to affect your laboratory, due to go into effect on December 28, 2024.

Changes to Acceptable Educational Degrees

When CMS opened the public comment period for these changes in 2018, laboratorians from all over the country expressed their thoughts in a lively debate about what place nursing degrees, physical science degrees and non-traditional degrees should have within the laboratory testing field. The results of these discussions led to the creation of an algorithm for laboratories and accreditation organizations (AOs) to use to determine whether degrees in subjects other than laboratory science meet the CLIA personnel requirements.

The regulations state that an individual must hold a degree in biology, chemistry, medical technology or clinical laboratory science. This may be a clear path for qualification for someone who holds a degree in microbiology or genetics, but sometimes it is harder to determine if a science major such as marine biology or biotechnology is enough to qualify a person to hold certain CLIA positions. With a new standard way to count semester hours (SH) as an alternative pathway, reviewing education qualifications will be more standardized across the board. In the past, the CLIA regulations had a way to count semester hours to determine equivalence to the appropriate associate level degree. Now, the new rule specifies how to count the SH to qualify someone with an appropriate bachelor level degree. The requirement is double what the associate level qualifications currently are: a minimum of 120 SH total from an accredited institution that also includes (1) 48 SH of medical laboratory technology or clinical laboratory science courses OR (2) 48 SH of science courses that include: 12 SH of chemistry (which must include general chemistry and either biochemistry or organic chemistry); 12 SH of biology (which must include general biology and molecular biology, cell biology or genetics); and 24 SH of additional chemistry, biology, medical laboratory technology or clinical laboratory science in any combination.

Many new testing personnel will be applying to laboratory positions in the future with science degrees that may not, at first glance, appear to meet the CLIA education requirements. With the addition of the bachelor's level SH count from a transcript, verifying a person's qualifications will be more straightforward. Just remember, when using a transcript to verify education: be sure that the date of graduation is present on the document!

Another notable change when it comes to the definitions of degrees is the clarification on doctoral degrees. These degrees must be earned post-baccalaureate degrees with at least three years of graduate level study that includes research related to clinical laboratory testing. This clarifies that honorary degrees do not meet the minimum qualifications. This laboratory work must be related to human medicine, which means that the Doctorate of Veterinary Medicine (DVM) degree will be removed as a qualifying pathway.

CMS is focusing primarily on degree programs where the individual will have an education that ensures they can operate and direct a CLIA laboratory – meaning that the Doctorate in Clinical Laboratory Science (DCLS) degree will be accepted under this definition. DCLS programs ensure that graduates will be able to handle all areas of the laboratory to ensure high quality results and will be able to direct laboratory operations to comply with all state and federal laws and regulations.
One last notable clarification on specific degrees - there were many comments and opinions on how a nursing degree should be considered within the CLIA regulations moving forward. Comments were heard and while nursing degrees will qualify someone for moderate complexity testing, an individual with a nursing degree alone will no longer be able to qualify for high complexity testing or laboratory director.

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Changes For Laboratory Directors

Next up, changes will directly affect the qualifying education requirements and responsibilities for laboratory directors. The main reasoning behind these changes is that laboratory director responsibility citations have been among the top ten condition level deficiencies in laboratories for many years. With the new rules for qualifications and responsibilities, CMS is hoping that laboratory directors will be more involved with their laboratories so that they can better report accurate and reliable test results. The main addition to the qualifications includes a requirement for all non-pathologist laboratory directors to take a course consisting of 20 continuing medical education (CME) credits related to laboratory director responsibilities, to help reinforce understanding of their overall responsibilities in a laboratory. This educational requirement will give all laboratory directors the knowledge and skills required to run a CLIA laboratory as the courses will cover CLIA compliance and the laboratory director's role in quality.

Another big change is a new requirement that all laboratory directors visit their laboratories onsite at least twice per year, with at least 4 months between visits. These visits must be documented onsite as they cannot be done virtually. Many laboratory directors work remotely and rarely go onsite to check in with the laboratory, which could be a contributing factor to increased citations during onsite biennial surveys. The laboratory director can decide how to document these visits, but acceptable documentation can include visitation logs, meeting minutes and summaries, notes of observations and travel vouchers.

Changes For Technical Consultants and Technical Supervisors

Now onto some news for the technical consultants and technical supervisors, where there are two key pieces of information worth sharing. Educational qualifications for technical consultants will be updated: personnel qualified to act as a general supervisor in a high complexity laboratory with their associate level education can now hold the technical consultant role in a moderate complexity laboratory, provided they also meet the experience requirement. Meaning, a person with an associate degree in medical laboratory technology or clinical laboratory science and at least 4 years of laboratory training or experience, or both, in nonwaived testing in the designated specialty or subspecialty areas of service can now perform the duties of the technical consultant. This includes completing competency assessments for testing personnel in their laboratories. This should be a huge relief to all laboratories that are understaffed, as the laboratory director can now delegate competency activities to a larger number of qualified individuals.

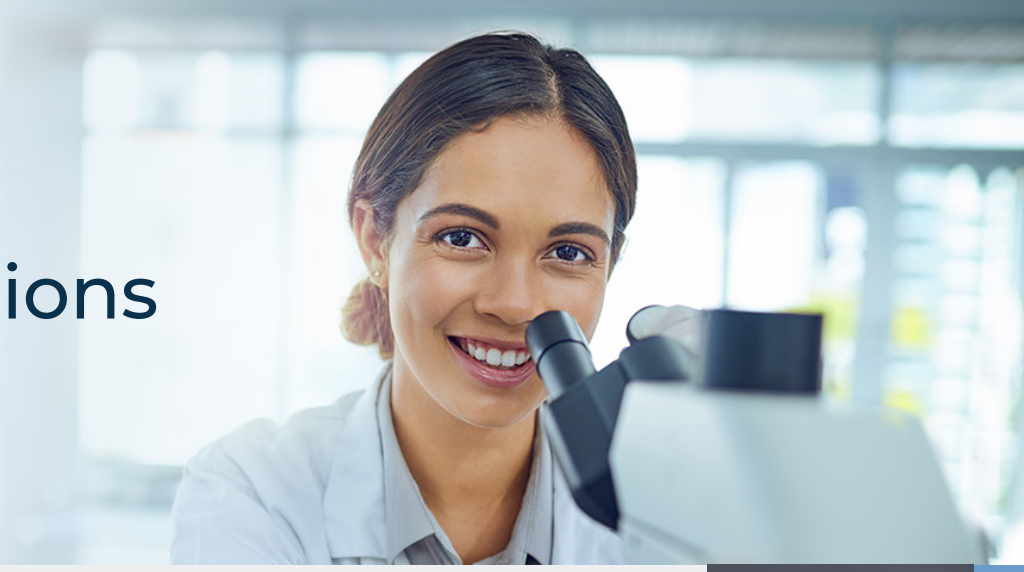
As for the technical supervisor role in full transfusion laboratories, the education qualifications have been updated here as well to align with the other high complexity specialties. Now a technical supervisor in immunohematology can have a doctoral, master or bachelor degree with the appropriate training and experience to qualify as a technical supervisor for immunohematology. This is another large help to laboratories that are short on staff, especially for small rural hospitals where the current qualified technical supervisor may not be onsite as they cover a large geographical area.

Overall, the new final rule that has been posted should ultimately help laboratories produce accurate and reliable patient results. Defining the education requirements while also giving more guidance on which types of science degrees qualify for laboratory testing will make the hiring process easier. Not only that, but more laboratory directors will now have the opportunity to learn more about their responsibilities (and their own laboratories) before they take on the role. The laboratory world is constantly changing, as is the workforce. While changes can be challenging, it is good to understand where they are coming from. Review the final rule in the Federal Register using the link below to find more in-depth reasoning behind each decision that is outlined here, or to view other changes that were not included in this summary.

Reference:

Frederal Register: https://www.federalregister.gov/documents/2023/12/28/2023-28170/clinical-laboratory-improvement-amendments-of-1988-clia-fees-histocompatibility-personnel-and

Top Ten Citations



By: Eamon Tiffany, BSN, MLS(ASCP)

Prior to joining COLA in 2017, Eamon Tiffany, MT (ASCP), BSN, was a General Supervisor at the University of Maryland Medical Center Midtown Campus for 14 years, overseeing the Core Laboratory, Transfusion Services, and Microbiology sections. He previously held the position of Senior Operations Manager at COLA, where he managed and supported surveyors and developed policies and process improvement strategies for the Accreditation Division.

Eamon earned a Bachelor of Science Degree in Medical Technology from Salisbury University in Salisbury, MD and a Bachelor of Science Degree in Nursing from Stevenson University in Pikesville, MD.

Running a laboratory is enough of a challenge in itself, with staffing shortages and emphasis on cost containment, but maintaining compliance with regulatory requirements should always be top of mind as well. Preparing your laboratory for a survey requires particular attention to detail. If your laboratory is fully accredited, it is important to review the results from previous surveys to identify issues that caused citations to be issued during those surveys. Even if your laboratory did not receive any citations during the most recent survey, it is still useful to act on any recommendations from past surveys to possibly avoid citations in the future.

As an accrediting organization, we are especially attuned to recognizing when laboratories are issued the same citations repeatedly. Our Surveyors provide guidance to assist laboratories with maintaining consistent compliance between surveys. For various reasons, such as turnover of staffing or new leadership, a laboratory can sometimes lose sight of compliance requirements leading to citations and occasionally repeated citations over several surveys. Repeated citations are a particular problem as they most often demonstrate a lack of general oversight of the laboratory. Below are some causes of repeated citations our Surveyors frequently encounter:

- Procedures are missing or incomplete
- Testing personnel do not have a full understanding of procedures
- Documents are not well organized
- Job descriptions are not clearly defined
- Testing personnel are inadequately trained
- There is insufficient communication between the laboratory director, technical consultant/technical supervisor and testing personnel

What are the most common repeated citations and what can laboratories do to avoid them?

The laboratory director not meeting proficiency testing responsibilities. The responsibilities include ensuring that:

- The laboratory is enrolled in a CMS-approved proficiency testing (PT) program for its regulated analytes.
- PT samples are tested in the same manner as patient samples.
- Proficiency testing results are submitted on time to the PT provider.
- Appropriate staff review the laboratory's performance results and a corrective action plan is followed when performance is unsatisfactory.
- PT samples are tested according to CLIA regulations prohibiting referral of specimens and communication of results.

◦ ***Steps to take to avoid this citation:***

- Create a schedule of all PT events with shipping and results submission dates.
- Create a rotating schedule of testing personnel to perform proficiency testing for each event.
- Review results with testing personnel immediately after receipt and document corrective action responses for any scores less than 100%.
- Ensure all proficiency testing requirements are addressed prior to a survey and sustained between surveys.

The laboratory director or technical supervisor/technical consultant does not follow written policies and procedures to periodically evaluate personnel performance and competency of all staff involved in preanalytic, analytic and postanalytic phases of testing, as well as those responsible for supervision and consultation.

- Competency assessment for all positions in the laboratory have not been completed or are missing one or more of the six CLIA-required elements (direct observation of routine patient test performance, monitoring the recording and reporting of test results, review of intermediate test results or worksheets, direct observation of performance of

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instrument maintenance and function checks, assessment of test performance and assessment of problem-solving skills).
- Competency assessments are not performed at required intervals: six months and one year after hiring and annually thereafter.
- Competency assessments are not performed for staff other than testing personnel, such as technical supervisor, general supervisor or technical consultant.

- ***Steps to take to avoid this citation:***
  - Create a schedule with competency due dates for all staff and schedule assessments with each staff member at least a month before the due date.
  - Retain records of documentation to support the six elements for at least two years.
  - The laboratory director can perform competency assessments on the technical supervisor, general supervisor or technical consultant.
  - If the laboratory director performs patient testing, the competency assessment can be performed by the technical supervisor, general supervisor (if delegated by the technical supervisor) or technical consultant.
  -

Laboratory employees do not adequately fulfill the responsibilities of their position. (Technical consultant/technical supervisor)

- Technical consultant/technical supervisor is responsible for:
- Enrollment in an appropriate PT program or developing a compliant split-sample analysis process.
- Monitoring quality control activities and corrective actions to failures.
- Evaluation and performance of competency assessments.

- ***Steps to take to avoid this citation:***
  - Have the technical consultant/technical supervisor review the laboratory's test menu at least annually to ensure compliance with PT requirements for each test.
  - Retain documents demonstrating the resolution of quality control failures and measures implemented to avoid future failures.
  - Document competency assessments for every position in the laboratory that include a detailed evaluation of each of the six required elements of competency for testing personnel.

Laboratory employees do not adequately fulfill the responsibilities of their position (Testing Personnel)

- Testing personnel are responsible for:
  - Performing testing as described in procedures.
  - Addressing quality control or test system failures before reporting patient results.
  - Documenting corrective actions.

- ***Steps to take to avoid this citation:***
  - Review testing procedures regularly, at least biennially, to compare current testing processes to written procedures.
  - Include quality control and test system failure scenarios in training and competencies to assess decision-making skills.
  - Develop standard processes and terminology for use by all staff to document measures taken to resolve issues.
  - Create an incident log to document corrective actions for future reference.

The proficiency testing attestation form was not signed by the laboratory director and the testing personnel

- The form can be signed by another qualified individual delegated by the laboratory director.
- The attestation must be signed by all staff involved in the testing of the event either electronically or manually, not printed.

- ***Steps to take to avoid this citation:***
  - Create a log sheet for each proficiency testing event that documents each step, including receipt of samples, testing, submission of results and reviewing results from the PT provider.
  - Plan on submitting results at least a few days prior to the submission deadline to allow extra time for gathering signatures of all testing personnel who performed testing.

Proficiency testing scores of less than 100% are not evaluated with documented appropriate corrective action.

- Even though a laboratory may have a passing score of 80% for a particular proficiency testing event, unacceptable results must be investigated to find the cause of the failures.
- ABO typing, Rh typing, compatibility testing and antibody screening require a score of 100% as a passing score.

- ***Steps to take to avoid this citation:***
  - Include a process in your PT procedure for investigating unacceptable proficiency testing results.
  - Retain all documentation of investigations for at least two years.
  - Share investigation findings with all testing personnel, including those who did not participate in the proficiency testing event.

The laboratory director does not meet the quality control and quality assessment responsibilities of the position. The responsibilities include:

- Oversight of the quality control and quality assessment programs to ensure identification and correction of failures are compliant with CLIA requirements.

- ***Steps to take to avoid this citation:***
  - Document reoccurring meetings between the laboratory director and technical supervisor/technical consultant to review quality assessment activities.
  - Schedule quality assessment reviews throughout the year with a focus on particular processes with each review to lessen the workload on staff.
  - Submit the technical supervisor/technical consultant's monthly review of quality control to the laboratory director for review.

Quality control data is not plotted or statistics are not calculated to monitor the accuracy and precision of testing over time.

- Quantitative quality control data should be displayed in a graphical form, such as a Levey-Jennings chart or monitored using statistical indices, CV, SD and mean.
- Review of data should be every week or 5-7 data points to identify trends or shifts before they become problematic.

- ***Steps to take to avoid this citation:***
  - Ensure testing personnel are assigned to review charts or indices on a weekly basis or every 5-7 data points with a secondary review by the technical supervisor, technical consultant or general supervisor.
  - Incorporate review of charts or indices in training and competency assessments.
  - Have the technical supervisor, technical consultant or general supervisor periodically review any significant trends or shifts with all staff.
  - Retain organized documentation, preferably in chronological order, with the signature or initials of the reviewer and the date.

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External split-specimen testing for unregulated analytes is not performed if not enrolled in a CMS-approved proficiency testing program.

- Develop a process to test five specimens twice per year for each test.
- Coordinate testing with a CLIA-certified laboratory.
- Establish acceptance parameters.

◦ Steps to take to avoid this citation:
  - Maintain a list of all unregulated analytes with documentation of which analytes are covered by a proficiency testing program and which require spilt-specimen analysis.
  - Maintain documentation of the establishment of acceptance parameters with signed and dated approval from the laboratory director.
  - Develop a step-by-step procedure for split-specimen analysis, including review of results and implementation of corrective actions for failures.
  - Establish a yearly schedule for each analyte that requires split-specimen analysis and assign specific testing personnel to each event.

The laboratory director does not meet the personnel management responsibilities of the position. The responsibilities include:

- Ensuring sufficient staffing based on testing volume and complexity of testing.
- Ensuring test personnel meet the CLIA requirements for education and experience for the testing performed.
- Defining job descriptions for each position in the laboratory which are appropriate based on CLIA requirements.

◦ Steps to take to avoid this citation:
  - Have the laboratory director and staff regularly track turnaround time metrics to assess appropriate staffing.
  - Create a manual or electronic filing system for staff educational documents and resumes for easy access.
  - Directly involve the laboratory director in evaluating the qualifications of new personnel.

The citations above are just a sampling of what our Surveyors issue to laboratories throughout a typical year. The common theme for the citations discussed and all citations related to regulatory requirements is that clear, open communication, in all forms, between all positions in the laboratory and with regulatory bodies is essential to providing high-quality care for patients.

Laboratories should constantly seek to improve their processes, even if they recently had a survey with no citations, to avoid becoming stagnant and resistant to the rapidly changing landscape of the clinical laboratory. Consistent review of the preanalytic, analytic and postanalytic processes in a laboratory is critical to reveal any weaknesses that could potentially cause a negative impact on patient care. Cultivating a culture of safety and compliance in the laboratory requires the commitment of every staff member.

Executives Convene 2nd Annual Summit to Address the Laboratory Workforce Shortage

By: Kathy Nucifora, MPH, MT(ASCP)

Kathy Nucifora joined COLA as the Accreditation Division Manager in November 2009 and in 2019 became COLA's Chief Operating Officer. Kathy was recruited from a COLA accredited lab, Hutchinson Clinic, to join Maryland General where she was responsible for creating and implementing new quality processes and procedures. In addition to managing the day to day operations of the lab, she developed and led a multidisciplinary task force to implement molecular testing for MRSA; she proposed and implemented a positive patient identification system via handheld computers; and helped lead the Laboratory and Nursing Process Improvement Committee. Kathy has also served as adjunct faculty at the Community College of Baltimore County for their Medical Laboratory Technician program.

On May 7, 2024, representatives from various organizations across the nation met in Destin-Fort Walton Beach, Florida for the second Annual Workforce Action Alliance (WAA) Summit. The WAA is an executive-level group focused on identifying a few key initiatives each year to address the laboratory workforce shortage.

During one of COLA's Annual Laboratory Enrichment Forums, the Workforce Action Alliance was conceived. COLA's COO, Ms. Kathy Nucifora, MPH, MLS (ASCP), asked attendees about more measures that could be taken to alleviate the crisis and the strain that laboratory science professionals and employers across the country were under due to the shortage. "Bring us all together" was the resounding reply.

While COLA took the step of "bringing us all together" by catalyzing and hosting the first Workforce Action Alliance Summit, the success is really attributed to WAA Summit Planning Committee members and all the volunteer executives. "The Alliance works because of the dedicated efforts of everyone who participates and the commitment to focus on no more than three initiatives at any one time," stated Ms. Nancy Stratton, COLA CEO. "The success of the WAA hinges not on any one organization but is the result of many executives working together," she added.

At this year's Summit in Destin-Fort Walton Beach, the group reconvened to assess the progress that has been made on the initiatives that were selected the previous year and to determine the objectives that would be pursued over the next twelve months.

During the opening session, key data was presented to better understand the laboratory workforce shortage. While the data analysis is complex, the workgroup reviewed the existing data with fresh eyes, set a plan in motion to gather more data and rather fortuitously found a new data reservoir to help close the gap. The workgroup is hopeful that their efforts will be beneficial to inform policy solutions and professional advocacy in a second year of effort.

The group also reviewed the results of the past year's efforts to visualize career paths for new and transitioning professionals, reach out to the next generation and the willingness to compromise which became necessary to coalesce around the nomenclature "laboratory science" as an overarching umbrella term, similar to "nursing," to encompass all aspects of the profession.

CONTINUED ON PAGE 13 »»

"The key measure of success for the Workforce Action Alliance is to identify actionable items and work towards improvement," stated Ms. Nucifora, Chair of the WAA Summit Planning Committee. "I believe many of us would agree that while there is much work that remains, the WAA Summit did create momentum in tackling the crisis together," she added.

In the afternoon, the group explored several key trends that will affect the workforce shortage and professional skills of the future, including artificial intelligence, robotics, value-based payment systems and emerging public health threats. "While working on the current crisis, it is important to consider how broader societal, reimbursement and technological trends may affect the future of the laboratory science workforce," shared Mark Birenbaum, PhD, Administrator, National Independent Laboratory Association & American Association for Bioanalysts.

Following a series of fruitful discussions, the group concluded that they would continue their work on two fronts and add a new initiative for action.

The three priorities for the next 12 months will be:The three priorities for the next 12 months will be:

1. Continuation of the workgroup that is collecting and analyzing data to better understand the laboratory workforce with a focus on translating insights into action
2. Continuation of the "Communicate Career Paths for New and Transitioning Professionals" workgroup and its subgroups
3. Understanding Future Trends for Laboratory Professional Skills Development and Reward

COLA and the Planning Committee members will develop and publish a written summary of the Summit Proceedings, which will be made available to the public this fall. The Summit Planning Committee includes representatives from the following organizations:

- American Society for Clinical Laboratory Science (ASCLS)
- American Society for Clinical Pathology (ASCP)
- American Society for Microbiology (ASM)
- National Society for Histotechnology (NSH)
- Centers for Disease Control and Prevention (CDC)
- American Association of Bioanalysts (AAB)
- National Independent Laboratory Association (NILA)
- Association for the Advancement of Blood and Biotherapies (AABB)
- Association of Public Health Laboratories (APHL)
- COLA

For more information about the working groups of the Workforce Action Alliance Summit, please email WAA@cola.org.

The WAA Planning Committee would like to thank the American Association of Bioanalysts Board of Registry (ABOR), the National Independent Laboratory Association (NILA) and COLA for their chartable financial contribution to help make the Summit possible.

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We are a physician-directed organization whose purpose is to promote health and safety through accreditation and educational programs.

ABOUT COLA:

COLA, Inc. is a physician-directed organization whose purpose is to promote health and safety through accreditation and educational programs. In 1993, COLA was granted deemed status by CMS to provide laboratory accreditation. As a leading laboratory accreditor in the United States, COLA operates its laboratory accreditation program in accordance with a quality management system certified to ISO 9001. This means we offer our customers a unique, standardized program and staff dedicated to satisfaction and laboratory quality. Our Surveyors and Technical Advisors are guided by a coaching approach and uncomplicated quality engineered processes. Laboratories of all types and sizes are evaluated and mentored to produce the highest quality laboratory services and meet CLIA regulations.

COLA's Board of Directors consists of representatives from three founding member organizations: the American Medical Association (AMA), American Academy of Family Physicians (AAFP) and the American College of Physicians (ACP).

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