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Association for the Advancement of Blood & Biotherapies

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Mehmet Oz MD, MBA
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–3485–NC
P.O. Box 8016
Baltimore, MD 21244–8016

Submitted via https://www.regulations.gov/docket/CMS-2026-2345

Re: Request for Information; Clinical Laboratory Improvement Amendments of 1988 (CLIA) Regulations (CMS-3485-NC)

Dear Dr. Oz:

The Association for the Advancement of Blood and Biotherapies (AABB) appreciates the opportunity to provide comments regarding the Clinical Laboratory Improvement Amendments (CLIA) Request for Information.

AABB is an international, not-for-profit organization representing individuals and institutions involved in the fields of transfusion medicine and biotherapies. The Association works collaboratively to advance the field through the development and delivery of standards, accreditation and education programs. AABB is dedicated to its mission of improving lives by making transfusion medicine and biotherapies safe, available and effective worldwide.

For the purpose of these comments, "laboratories" are defined to include blood banks and transfusion services, immunohematology reference laboratories (IRLs), molecular testing laboratories, human leukocyte antigen (HLA) laboratories, flow cytometry laboratories, donor testing laboratories, perioperative services, and cellular therapy laboratories.

AABB supports modernization efforts that appropriately recognize advances in laboratory medicine while preserving flexibility, avoiding duplicative regulation, and maintaining a risk-based approach to oversight. Laboratory professionals play a leading role in quality management, take responsibility, and operate under an extensive regulatory framework. Laboratories are all part of federal, state, or locally licensed facilities and satisfy relevant licensure requirements. They are subject to several federal regulatory frameworks (i.e., CLIA, FDA regulations, the Occupational Safety and Health Administration (OSHA) regulations, etc.) and state regulations.

In addition, the quality and safety of care provided by these laboratories is supported and continuously validated by accreditation programs. For example, AABB-accredited laboratories adhere to longstanding and internationally recognized standards that evaluate the facility's quality management system and provide tools to monitor performance, capture deviations, and analyze suboptimal outcomes. The standards define current responsibilities and relate to organizational requirements; resources; equipment; supplier and customer issues; agreements;

process control; documents and records; deviations, nonconformances, and adverse events; internal and external assessments; process improvement; and safety and facilities.[1]

CLIA modernization should remain risk-based, technology-neutral, and non-duplicative. AABB is committed to continuing to work with CMS to modernize the CLIA regulations to reflect advances in practices, such as immunohematology, molecular testing, electronic crossmatching, and laboratory informatics, while avoiding prescriptive requirements that increase burden, worsen and/or strain workforce shortages, or duplicate existing requirements.

Section B. Laboratory Processes and Procedures

B.2 Specimen Preparation Activities and Personnel

1. **What activities does the laboratory consider to be part of specimen preparation (for example, centrifuging, aliquoting, loading on analyzers, adding chemicals for preparation, tissue processing, slide staining, inoculating culture plates, DNA/RNA extraction)?**

Specimen preparation activities play an essential role in transfusion medicine, donor testing, histocompatibility, molecular testing, and cellular therapy laboratories. Activities may include patient and donor identification, specimen labeling, specimen receipt and evaluation of suitability, and accessioning, centrifugation, aliquoting, preparation for automated analyzers, nucleic acid extraction, preparation for molecular testing, and sample handling necessary to support complex testing workflows.

2. **What is the education and experience of the personnel who perform specimen preparation activities for your laboratory?**

Personnel who perform specimen preparation activities in laboratories possess a range of education, training, and experience levels that are commensurate with the complexity and risk of their specific duties. These individuals may include medical laboratory assistants, phlebotomists, medical laboratory technicians, medical laboratory scientists, and experienced technologists. Education backgrounds vary widely and may include high school diploma with on-the-job training, certificate or associate degree programs in phlebotomy or medical laboratory technology, and bachelor's, master's, or doctoral degrees in clinical laboratory science and specialized disciplines such as molecular biology, immunology, and genetics.

Laboratories utilize competency-based personnel qualification systems supported by documented education, training, supervision, and periodic competency assessment. Accreditation organizations, such as AABB, assess these factors to ensure that personnel, including those who perform specimen preparation activities, are qualified to perform their roles. For example, *AABB Standards for Blood Banks and Transfusion Services* require personnel performing critical tasks to be appropriately qualified, trained, and periodically assessed for competency (*AABB Standards* 2.1.2 - 2.1.4).

[1] See AABB Standards, available at https://www.aabb.org/standards-accreditation/standards.

This competency-based approach, rather than prescriptive educational requirements, allows laboratories to match qualification levels to actual job duties while ensuring all personnel meet documented competency standards appropriate to their work.

3. **What types of training does the laboratory provide for the personnel who perform specimen preparation activities?**

Personnel qualifications should remain commensurate with the complexity and risk associated with the activities performed. Existing laboratory quality systems effectively ensure that personnel are trained and competent, while allowing laboratories flexibility to address local workforce considerations and operational needs. Accreditation organizations, such as AABB, require laboratories to develop and implement training programs appropriate to employee roles and responsibilities (e.g., *AABB Standards for Blood Banks and Transfusion Services*, Standard 2.1.3). These programs ensure that personnel are qualified and competent before performing critical tasks.

CMS should preserve flexibility in personnel qualification requirements and continue to support competency-based approaches rather than imposing new prescriptive educational or credentialing requirements. Additional personnel mandates could exacerbate existing workforce shortages without providing measurable improvements in testing quality or patient safety.

4. **How does the laboratory ensure that personnel who perform specimen preparation activities remain competent?**

As mentioned previously, laboratories ensure ongoing competency of personnel performing specimen preparation activities through their competency-based personnel qualification systems, which include documented education, training, supervision, and periodic competency assessment.

Accreditation organizations, such as AABB, ensure that accredited laboratories have policies and procedures in place to continuously assess the competency of laboratory personnel. For example, *AABB Standards* require competency before independent performance of assigned activities and at specified intervals thereafter (e.g., *AABB Standard* 2.1.4). These competency-based approaches have proven effective across diverse laboratory settings and complexities.

B.3 Suboptimal Specimens

1. **What are the circumstances under which the laboratory tests suboptimal specimens?**

Laboratories frequently encounter situations in which specimen acceptability considerations must be balanced against urgent patient care needs. Existing policies and procedures provide laboratories with the flexibility to assess specimen quality, document limitations, communicate with ordering providers, and determine whether testing can safely proceed. Such flexibility is particularly important in emergency transfusion situations where delaying testing may create greater patient risk than testing a specimen with documented limitations.

2. **How often does your laboratory test suboptimal specimens annually?**

Suboptimal specimens are encountered routinely in laboratory practice, but they represent a very small percentage of overall specimen volume. The frequency varies by laboratory based on patient population, collection setting, and specimen type. Laboratories routinely monitor specimen quality indicators as part of their quality management programs and employ established processes to identify and address specimens that do not meet acceptance criteria.

In the transfusion service setting, the impact of suboptimal specimen suitability, including specimen mislabeling, is further mitigated by the availability of alternatives to testing suboptimal specimens. For example, the transfusion service may issue uncrossmatched red blood cells or group O and other universal-donor components under established emergency release procedures when clinically appropriate. In addition, laboratories employ safeguards designed to detect potential specimen identification errors, including repeat ABO testing and comparison with historical ABO records. These measures, which are commonly tracked through laboratory quality systems, provide additional layers of protection and help ensure patient safety when suboptimal specimens are encountered.

Laboratories employ risk-based approaches to specimen evaluation that consider patient safety, clinical urgency, testing limitations, and quality management requirements. This risk-based framework allows laboratories to exercise professional judgment regarding suboptimal specimens while requiring appropriate documentation, provider communication, and quality management oversight. For example, individual laboratories may define this testing exception as a key performance indicator, use this data in risk assessments, and track the origin of suboptimal specimens to develop intervention strategies.

3. **How does the laboratory document and report results from suboptimal specimens?**

Laboratories employ risk-based approaches to identify and document specimen quality issues and communicate limitations to ordering providers, as needed. Documentation and follow-up activities are guided by existing quality management systems. Depending on the nature of the issue and potential impact on test results, specimen recollection may or may not be necessary. When testing is determined to be acceptable, laboratories may include comments or other notifications in the test report to inform the ordering provider of the specimen limitation.

4. **How does the laboratory communicate with ordering providers regarding suboptimal specimens?**

Notification of a suboptimal specimen may occur through multiple channels, such as telephone contact, electronic health record notifications/documentation, supplemental comments on reports, and consultation with clinical providers. Laboratories use different communication methods, which may depend on factors such as clinical urgency, institutional relationships, testing limitations, and quality management requirements. As recollecting laboratory specimens may or may not be necessary, laboratories may add a comment about the specimen issue to inform the ordering physician.

5. **What quality assurance measures does the laboratory apply to the testing of suboptimal specimens?**

Laboratories have standard processes and procedures that validate specimens with different types of issues and establish limits on when the issue will yield accurate results (and thus testing should proceed) or when the issue renders the sample unusable. As recollecting laboratory specimens may or may not be necessary, laboratories may add a comment about the specimen issue to inform the ordering physician.

6. **What challenges does the laboratory face in managing suboptimal specimens while ensuring test result quality?**

Emergency transfusion situations pose challenges since delayed testing may create greater patient risk than testing a specimen with documented limitations. Laboratories manage these challenges by leveraging risk-based approaches to specimen evaluation that consider patient safety, clinical urgency, testing limitations, and quality management requirements.

B.4 Establishment and Verification of Performance Specifications

1. **For tests that are not FDA-cleared or approved, including modifications of FDA-cleared or approved tests, what challenges does the laboratory encounter when establishing adequate performance specifications and appropriate acceptance criteria?**

Laboratories routinely establish and verify performance specifications for highly specialized testing methodologies, such as molecular blood group genotyping, HLA testing, antibody characterization, platelet immunology testing, chimerism analysis, and other transfusion-related applications. They may provide patients with access to accurate and high-quality laboratory tests for conditions for which no commercial test exists or where an existing test does not meet clinical needs. A laboratory may customize and validate a test to meet the individual needs of a patient or may use reagents that are not licensed, approved, or cleared by FDA. Additionally, the tests may be manual, automated, or hybrid.

Some established laboratory practices and procedures are reflected in authoritative resources used by laboratory professionals, such as the AABB Technical Manual. Examples include, but are not limited to:

- Method 3-18 Treating Red Cells Using DTT or AET
- Method 3-19 Neutralizing Anti-Sda with Urine
- Method 3-20 Adsorption procedure
- Method 4-2 Glycine-HCl/EDTA Elution Procedure
- Method 4-9 Adsorbing Warm-Reactive Autoantibodies Using Allogeneic Red Cells
- Method 4-11 Performing the Donath-Landsteiner Test
- Method 4-12 Detecting Drug Antibodies by Testing Drug-Treated cells

- Method 5-2 Testing for Fetomaternal Hemorrhage – Modified Kleihauer-Betke test[2]

Existing accreditation programs, such as AABB's accreditation framework, require organizations to validate new or changed processes before implementation and establish objective evidence that performance specifications have been met (e.g., *AABB Standards* 5.1.1, 5.1.4- 5.1.5). These validation requirements have successfully supported implementation of molecular testing, specialized immunohematology testing, and other novel methodologies without the need for highly prescriptive technical specifications.

We recommend that CMS preserve flexibility for laboratories to establish scientifically appropriate, fit-for-purpose performance specifications based on intended use, available evidence, patient need and advancements in technology and instrumentation. Future CLIA updates should remain risk-based and technology-neutral, avoiding overly prescriptive validation requirements that could negatively affect access to specialized testing services. Technology evolves rapidly, and prescriptive approaches may become obsolete within a short timeframe.

3. How does the laboratory currently design, develop, and prepare reagents for tests developed in-house?

Laboratories design, develop, and prepare reagents for tests developed in-house using scientifically rigorous and well-established processes that are performed under laboratory quality management systems. Reagent development is informed by peer-reviewed scientific literature, validated laboratory procedures, and authoritative professional resources, including the *AABB Technical Manual* and the *AABB Standards*. Laboratories evaluate and document reagent performance characteristics, establish appropriate quality control measures, and verify that reagents are suitable for their intended use before implementation. These activities are conducted by qualified laboratory professionals and are subject to ongoing monitoring to ensure continued test performance, accuracy, and patient safety.

4. What types of modifications does the laboratory commonly make to FDA-cleared or approved test systems?

See response to question 1 above.

B.5 Calibration Verification

1. What technical and operational challenges does the laboratory face when performing calibration verification on FDA-cleared or approved manufacturer-calibrated devices?

Many contemporary testing systems used in transfusion medicine and related areas employ manufacturer-controlled calibration processes and closed-system designs. Application of traditional calibration verification concepts to these systems may present challenges because

[2] See e.g., Cohn, C., Delaney, M., Johnson, S. et. al. AABB Technical Manual, 21st Edition: Methods and Appendices. (2023), available at https://www.aabb.org/aabb-store/resources/technical-manual-methods.

laboratories often cannot modify or independently adjust calibration parameters beyond manufacturer-established controls.

B.6 Postanalytic Interpretation and Use of Artificial Intelligence (AI)

In July 2026, CMS published in the Federal Register three separate actions related to laboratory practice and laboratories' use of software algorithms and artificial intelligence (AI) tools: (1) the CY 2027 Hospital Outpatient Prospective Payment System proposed rule (CMS-1850-P) (OPPS); (2) the CY 2027 Physician Fee Schedule proposed rule (CMS-1848-P) (PFS); and (3) a request for information on the Clinical Laboratory Improvement Amendments (CLIA) (CMS-3485-NC). There is overlap between the questions in the RFI and the proposed payment policies.

AABB encourages CMS to work with the laboratory community to assess and better understand the clinical, operational and regulatory issues associated with these technologies before making policy changes. It is critical that CMS work with stakeholders to identify long-term policy solutions that reflect the complexities of algorithmic technologies in laboratory medicine.

1. **How does the laboratory use software algorithms or AI tools in the postanalytic process?**

There is significant variability in how laboratories use algorithms or AI tools in the postanalytic process. These tools are not a single category. Rather they range from established, deterministic software, to predictive models, to adaptive models, to generative systems. They also vary with respect to advisory versus autonomous functions.

While AI is a tool that supports laboratory testing, data analysis, and result interpretation, it does not exercise independent clinical or professional judgment and should not be relied upon to render decisions that affect patient care. The practice of laboratory medicine is carried out by qualified healthcare professionals, including pathologists, blood banking/transfusion medicine physicians, other physician specialists, and appropriately trained advance practice providers and laboratory professionals.[3] Any AI-generated result, interpretation, or flag should be reviewed and confirmed by a qualified, laboratory professional who retains responsibility and accountability for the final result and its clinical interpretation.

Software algorithms and AI technology are evolving rapidly. Existing quality systems address software validation, performance verification, change management, data integrity, audit controls, and ongoing monitoring (e.g., *AABB Standards* 3.6 - 3.6.1). We encourage CMS to focus on the quality and accountability structure that surrounds these tools, such as qualified human review, validation, and documentation, rather than on prescribing specific technologies or methods that may be superseded before a rule takes effect.

[3] See ACGME Program Requirements, FAQs, and Applications for Pathology Specialties, available at https://www.acgme.org/specialties/pathology/program-requirements-and-faqs-and-applications/.

4. **What methods do laboratories use to verify the performance of the software functions (including image resolution accuracy and quality, and AI tools as well as the performance of computers and monitors) used with a test system?**

Test cases are developed and these test cases are run through the dry bench software programs and platforms to ascertain the functionality of the software with different example cases. This type of testing is iterative, building on each software program, until the full software pipeline is constructed and cases are run from end to end to test potential result situations.

5. **Are there additional technology considerations for high complexity tests including but not limited to laboratory use of automation, laboratory use of cloud analytics, and laboratory use of artificial intelligence that CMS and the CDC should consider incorporating into the CLIA regulations?**

CMS should adopt a technology-neutral regulatory framework focused on intended use, validation, and performance rather than creating AI-specific requirements that could inadvertently encompass long-established laboratory software systems, electronic medical records (EMRs), and transfusion medicine technologies. Accredited laboratories adhere to comprehensive information system requirements, reducing the need for AI-specific regulatory frameworks (e.g*., AABB Standards* 3.6 - 3.7*)*.

B.8 Remote Direct Observation Competency Assessment

1. **How does the laboratory currently use remote direct observation for competency assessment?**

AABB supports the use of remote direct observation as a valuable option for competency assessment, particularly for geographically dispersed organizations, rural facilities, and multi-site blood centers and laboratories.

2. **What types of devices (for example, smartphones, tablets, virtual reality devices/glasses, and dedicated video systems) does the laboratory currently use for remote direct observation for competency assessment?**

Laboratories may use secure video platforms, tablets, smartphones, webcams, and similar technologies to observe testing activities, specimen handling, equipment operation, and adherence to procedures.

3. **What challenges or limitations does the laboratory encounter with remote direct observation for competency assessment?**

Remote observation can improve access to qualified assessors and reduce operational burden. Activities requiring close evaluation of manual techniques or the laboratory environment may be more difficult to assess remotely. In these cases, remote observation may be most effective when used as one component of a risk-based approach of competency assessment. This allows

laboratories to determine which activities are suitable for remote assessment and which require direct, in-person observation.

Section C Emergency Preparedness, Biosafety and Biosecurity, and Cybersecurity

C.1 Emergency Preparedness

1. What are the best practices for laboratory emergency preparedness?

Laboratories maintain extensive emergency preparedness programs and many laboratories are subject to existing state and federal regulatory requirements that must be considered and incorporated into emergency preparedness plans and protocols. Additionally, accreditation organizations, such as AABB, require facilities to have emergency preparedness plans and protocols (e.g. *AABB Standards* 1.5 - 1.6.1).

Examples of preparedness activities include risk assessments, continuity of operations planning, inventory management, supplier redundancy, backup communications, transportation contingency planning, emergency donor recruitment, cold-chain preservation, and coordination with healthcare coalitions and public health agencies.

2. What challenges does the laboratory face in maintaining operations during emergencies such as natural and human-caused disasters, facility emergencies, and emerging infectious diseases?

Laboratories face challenges with supply chain disruptions and logistics interruptions. Additionally staffing challenges, already an issue given financial and workforce constraints, are exacerbated during an emergency. Ensuring full coordination and integration with regional healthcare coalitions, hospital preparedness programs, and the broader emergency preparedness and response infrastructure are necessary to support hospitalized patients prior to the catastrophic event and accommodate patients that have been injured during a disaster.

3. What elements does the laboratory include in its current emergency preparedness plans and protocols?

Emergency preparedness plans and protocols vary among laboratories based on a variety of factors, such as facility location, applicable federal and state regulations, accreditation standards, and institutional requirements. There is a complex, overlapping regulatory landscape, as laboratories must simultaneously comply with emergency preparedness requirements established by CMS, FDA, OSHA, state health departments, institutional emergency management programs, and accreditation organizations.

Requirements for emergency preparedness plans and protocols should be scalable, risk-based, and adaptable to the wide variety of laboratories subject to CLIA. Harmonization of requirements across regulatory agencies would provide clearer guidance to laboratories and improve emergency preparedness efforts and outcomes. When multiple agencies impose overlapping or duplicative preparedness obligations, laboratories must devote significant

resources to reconciling, documenting, and demonstrating compliance with substantially similar requirements. This duplication consumes valuable staff time, financial resources, and administrative effort that could otherwise be directed toward patient care. Importantly, duplicative requirements do not necessarily improve patient safety or preparedness outcomes.

4. What lessons has the laboratory learned from recent emergency situations?

Recent emergencies have reinforced the importance of workforce adequacy, supply chain resilience, information technology preparedness, cybersecurity planning, and the need for laboratories to coordinate with and be integrated in regional healthcare coalitions, hospital preparedness programs, and the broader emergency preparedness and response infrastructure.

C.2 Biosafety and Biosecurity

1. What challenges does the laboratory face in biosafety and biosecurity?

Challenges vary by laboratory type and are best addressed through flexible, risk-based approaches.

2. What elements or best practices does the laboratory include in its current biosafety and biosecurity plans and protocols?

In general, laboratories maintain comprehensive biosafety and biosecurity programs that include risk assessments, training programs, competency evaluation, exposure response procedures, engineering controls, and continuous quality improvement activities. These programs are tailored to laboratory-specific risks, operational complexity, and applicable regulatory requirements. Additionally, accreditation programs ensure that laboratories adhere to standards that address biological safety (e.g., *AABB Standards* 10.2 - 10.3).

3. How does the laboratory train personnel on biosafety and biosecurity plans and protocols?

Clinical laboratories train personnel on biosafety and biosecurity plans and protocols through a risk-based program that includes initial orientation, procedure-specific training, periodic refresher training, and training whenever policies or procedures are revised. Training is tailored to personnel responsibilities and typically covers topics such as safe specimen handling, hazard recognition, use of personal protective equipment (PPE), exposure prevention, decontamination and waste management procedures, incident reporting, emergency response, access controls, and measures to protect biological materials and related information from loss, theft, misuse, or unauthorized access. Personnel must demonstrate understanding and competency before independently performing assigned activities. Competency is reassessed at defined intervals to ensure continued proficiency.

C.3 Cybersecurity

1. What cybersecurity protocols/policies does the laboratory have in place to protect patient data and laboratory operations?

Laboratories depend heavily on interconnected information systems, including Blood Establishment Computer Systems (BECS), laboratory information systems, middleware applications, analyzer interfaces, and electronic health record integrations. Cybersecurity programs typically include access controls, identity management, monitoring, incident response planning, training, business continuity measures, and protection of sensitive health information.

Laboratories must align IT security governance with HIPAA compliance, NIST standards, organizational cybersecurity frameworks, and broader healthcare IT governance structures. Additionally, existing quality systems and accreditation frameworks require information security controls and technology resilience. For example, AABB-accredited laboratories are required to have controls for unauthorized access, mitigation of data breaches, data integrity, backup and recovery, security of electronic records, and monitoring of technology infrastructure (e.g., *AABB Standards* 3.6, 3.6.4, 3.6.5, 3.7, 6.3.1 - 6.3.4).

1.a. What is the frequency and process you follow to verify new or existing user identity and access requirements?

New user identities and access requirements are verified before access is granted. Existing user accounts and access privileges are reviewed at defined intervals and whenever there is a change in job responsibilities, employment status, or system requirements. Access is limited to the minimum necessary to perform assigned duties, and inactive or terminated accounts are promptly disabled.

2. What challenges or experiences has the laboratory faced in maintaining cybersecurity?

Examples of challenges related to cybersecurity include the rapid evolution of threats, personnel training and awareness, vendor and third-party risk management, balancing security with system usability and workflow efficiency, and resource constraints. As cybersecurity threats continue to evolve, laboratories require flexibility to implement security solutions appropriate for their size, complexity, and technological environment.

Cybersecurity is fundamentally an enterprise information technology and healthcare system issue that extends across all healthcare entities. IT security governance is distinct, and governed by HIPAA, NIST, organizational cybersecurity frameworks, and broader healthcare IT governance structures. AABB recommends that cybersecurity continue to be governed through harmonized, organization-wide frameworks rather than duplicative, CLIA-specific technical mandates. Laboratories cannot be expected to serve as the mechanism through which CMS addresses systemwide healthcare cybersecurity challenges.

3. Which laboratory job position(s) is responsible for cybersecurity in the laboratory?

The position responsible for cybersecurity in the laboratory varies depending on the unique characteristics of the laboratory and its organization.

D Specialty Testing Areas

D.1 General

1. **What specific challenges or limitations, if any, does your laboratory currently experience with the test specialty and subspecialty categories in the CLIA regulations? For example, are there areas where existing CLIA test specialty and subspecialty categories could be revised to better reflect current laboratory testing practices?**

The current specialty framework should be carefully modernized to reflect advances in molecular diagnostics, molecular immunohematology, histocompatibility testing, transfusion informatics, cellular therapy, and laboratory automation. Existing specialty structures generally remain appropriate; however, regulatory language can better reflect contemporary laboratory practice.

2. **Are there additional specialties or subspecialties that CMS and the CDC should consider incorporating into the CLIA regulations to ensure comprehensive oversight of laboratory testing as specialties evolve? Provide evidence-based rationale supporting their inclusion, including considerations related to patient safety, testing complexity, and public health impact?**

Based on currently available information, AABB does not believe that the creation of numerous additional specialty categories is warranted. Rather, creating new specialty categories has the potential to increase complexity without corresponding improvements in patient safety.

D.3 Immunohematology

1. **What immunohematology practices and technologies does the laboratory currently use?**

The practice of immunohematology has evolved significantly since the CLIA regulations were implemented. Contemporary transfusion services routinely employ automated blood typing and antibody screening platforms, molecular blood group genotyping, advanced antibody identification methodologies, electronic crossmatch systems, sophisticated BECS, and integrated health information technologies.

2. **What, if any, challenges does the laboratory face with existing CLIA regulations for immunohematology?**

The principal challenge associated with existing CLIA regulations for immunohematology is that current regulatory language does not fully reflect modern transfusion medicine practice or the technologies routinely used in immunohematology.

Immunohematology is subject to extensive oversight under both CLIA and FDA. We encourage CMS and CDC to prioritize harmonizing CLIA requirements and FDA regulations rather than adding new or duplicative requirements. Blood availability and safety are essential components

of the nation's public health infrastructure, and immunohematology laboratories maintain a consistently high level of quality under the current framework. Additional or more prescriptive requirements have the potential to add more burden without improving quality or patient care.

3. What operational challenges does the laboratory face with electronic crossmatches?

Electronic crossmatching has become a mature, widely accepted technology that provides substantial patient safety and operational benefits when implemented within validated systems. Operational considerations focus primarily on software validation, change management, interoperability, data integrity, business continuity, user training, and system performance monitoring. These operational challenges are well understood and effectively managed within existing quality frameworks. For example, AABB Standards have long recognized computer-assisted compatibility testing (e.g., *AABB Standards* 3.6, 3.6.1, 5.16.2, 5.16.2.1 - 5.16.2.4).

4. What type of quality assurance issues does the laboratory encounter in electronic crossmatch compared to the traditional serologic crossmatch?

Quality assurance programs for electronic crossmatching emphasize validation, audit trails, interface verification, user access controls, and ongoing monitoring rather than direct observation of serologic reactions. These quality assurance approaches are distinct from traditional crossmatching processes but have proven effective and appropriate.

D.4 Microbiology

1. What best practices has the laboratory implemented to reduce and monitor blood culture contamination?

Laboratories and blood establishments employ comprehensive quality systems to reduce and monitor the risk of blood component contamination. These include donor screening, skin disinfection, diversion of the initial collection volume, bacterial risk mitigation through pathogen reduction technologies, sterility testing, contamination monitoring, corrective action processes, trend analysis, and continuous quality improvement. These activities contribute significantly to patient safety and support the safe collection, processing, and distribution of blood components.

2. What challenges does the laboratory face in maintaining low blood culture contamination rates?

The laboratory faces several challenges in maintaining low rates of blood component contamination, including the potential for bacterial contamination during blood product collection, handling and processing. In addition, platelet units are stored at room temperature which creates an environment that can support bacterial growth. Other challenges include implementing evolving testing and risk-reduction technologies, and balancing inventory availability with product safety requirements. Importantly, laboratories mitigate these risks through multiple safeguards including consistent adherence to standardized procedures for collection and aseptic techniques, maintaining appropriate supplies and properly maintained equipment, ongoing quality monitoring, and personnel training on current best practices and comprehensive competency assessment.

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AABB appreciates the opportunity to provide input on this Request for Information and looks forward to continuing to engage with CMS and CDC as the agencies evaluate potential CLIA modernization initiatives. If you have any questions or need additional information, please contact me at lmstone@aabb.org.

Sincerely,

Leah Stone
Vice President, Public Policy and Advocacy
Association for the Advancement of Blood & Biotherapies