ADLM Association for Diagnostics & Laboratory Medicine™

POSITION STATEMENT

Advancing Laboratory Medicine Through Consistent Data and Responsible Oversight

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Introduction

Artificial intelligence (AI), including machine learning (ML) and generative AI, has the potential to transform laboratory medicine by enhancing diagnostic accuracy, improving efficiency, and enabling more precise, data-driven clinical decision-making. As AI tools are increasingly embedded in laboratory workflows, clinical decision support systems, risk prediction models, and population health applications, their influence on patient care continues to expand. The safety and effectiveness of these tools, however, depend on how they are developed, implemented, and overseen within clinical practice. In laboratory medicine, AI systems rely on complex diagnostic data and are increasingly positioned to influence clinical interpretation and decision-making, raising important considerations related to data quality, professional oversight, and governance.

This document focuses on the use of AI tools for prediction or classification that rely on laboratory data. It describes policy considerations that affect the performance, reliability, and equity of AI systems in laboratory medicine, while acknowledging that additional issues unique to emerging generative AI tools—such as large language models—are outside the scope of this discussion. Issues such as the use of generative AI applications, individual data privacy, and policies regarding patient disclosure when AI models contribute to clinical decision-making are also outside the scope of this discussion.

Background

Clinical laboratories operate under rigorous quality management systems that encompass method validation and continuous performance monitoring. These frameworks ensure that the billions of test results reported each year in the United States are accurate, dependable, and clinically meaningful. As AI systems are increasingly applied to analyzing laboratory data, embedded in laboratory workflows, clinical decision support tools, risk prediction models, and population health applications—the need for similarly robust oversight becomes even more critical.

Key Recommendations:

1. Modernize laboratory regulation for AI
2. Advance harmonization of laboratory data
3. Mitigate bias and promote data diversity
4. Establish AI validation and verification standards
5. Require continuous performance monitoring

Considerations

For AI to be safely and effectively implemented in laboratory medicine, several key issues must be addressed. These include establishing appropriate oversight mechanisms, improving data harmonization, mitigating bias, and ensuring robust validation and monitoring of AI systems.

Regulation and Oversight

AI and ML technologies vary widely in their potential to affect patient outcomes. Tools that directly influence diagnosis, treatment decisions, or test interpretation carry higher risks than those automating administrative or operational functions. Risk-based oversight approaches that scale to the severity and likelihood of potential harm should therefore form the foundation of regulatory policy for these tools.

In clinical laboratories, the Clinical Laboratory Improvement Amendments (CLIA) already require laboratories to validate and monitor test systems to

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ensure their accuracy, precision, reportable ranges, and reference intervals before and during clinical use. Although current CLIA regulations do not explicitly address AI systems, modernizing CLIA can provide the needed oversight for laboratory-developed AI services without creating a duplicative regulatory framework.

The Role of Harmonization in AI Development

AI systems that use laboratory data often assume that inputs are comparable across different sites and methods. In practice, this is not always the case. Different assays, platforms, and calibration approaches can produce different numeric results for the same analyte, even when each method is individually accurate. Without harmonization, these differences can:

- Degrade model performance when data are pooled across institutions;
- Limit an algorithm's generalizability to new sites or populations;
- Introduce systematic errors into risk scores and clinical decision support systems that depend on numeric thresholds; and
- Complicate efforts to evaluate AI performance across diverse health systems.

Global and national guidance on AI in health stress that limited, low-quality, or inconsistent data can produce biased inferences and unsafe results in clinical applications. In laboratory medicine, ongoing harmonization initiatives—for example, the CDC's standardization programs for cholesterol and hemoglobin A1c—show that aligning methods and reference systems improves comparability and underpins evidence-based interpretation.

Addressing Bias in Laboratory AI

Bias is one of the most widely recognized risks of AI/ML applications in healthcare. In laboratory medicine, two categories of bias-related risk are especially important:

- **Demographic underrepresentation and skewed clinical data:** Historical datasets may underrepresent certain racial and ethnic groups, age ranges, or socioeconomic strata. Studies of health AI tools have demonstrated that such imbalances can cause models to systematically under-estimate risk or misclassify disease in certain populations.

- **Technical variability and context mismatch:** Inconsistent calibration, different pre-analytical protocols, or outdated diagnostic criteria can change how a given laboratory value reflects underlying physiology. If AI models are trained on data from one set of methods then applied in a different environment without adjustment, they may misinterpret results or fail to generalize. These differences can cause algorithms to misinterpret patient health indicators when used across different clinical practices.

A variety of strategies should be considered to mitigate these issues, such as:

- Using diverse and representative patient datasets in AI model training and validation;
- Creating uniform guidelines for sample collection and reporting;
- Harmonizing results across measurement systems;
- Including metadata on test methods and validation parameters in AI models;
- Validating AI models across diverse clinical settings; and
- Engaging clinicians, laboratorians, and patients to identify sources of variability.

Implementation of such measures could ensure that laboratory-based AI promotes equity, fairness, and patient trust.

Validation and Verification of AI Systems in Laboratory Medicine

Under CLIA, clinical laboratories must validate new test systems before use and conduct ongoing quality monitoring—including daily quality control (QC), proficiency testing, and trend analysis—to ensure that performance remains within acceptable limits over time.
AI systems that rely on or influence laboratory data introduce similar risks. Notably, models that continuously update or "learn" from new inputs can drift in accuracy, calibration, or bias over time. Additionally, even if AI models are kept constant, changes in analytical instrument performance or patient characteristics over time may degrade their ability to produce accurate diagnostic results.
To effectively verify and monitor AI performance, laboratory professionals require sufficient access to the relevant data and model information from developers. Independent evaluation of a system's performance without transparency is challenging and can undermine ongoing quality assurance efforts. To address these considerations, several policy needs should be considered:

- Providing clear federal guidance informed by professional expertise on validation expectations for the AI tools used in laboratory

medicine, including requirements for documenting each tool's intended use, performance characteristics, and limitations.

- Enumerating the roles and responsibilities of laboratories, developers, and healthcare organizations in implementing, monitoring, and updating AI systems.
- Mandating ongoing performance monitoring of clinical decision support systems and AI/ML applications to ensure continued accuracy, safety, and equity across diverse patient populations and laboratory settings.

Oversight should correspond to the level of risk and potential impact an AI tool may have on patient outcomes. High-risk diagnostic applications—particularly those that influence clinical decisions or rely heavily on laboratory data should undergo robust validation, maintain transparency, and incorporate continuous monitoring. Lower-risk tools may warrant a more streamlined oversight process consistent with their reduced potential for patient harm.

Positions

Congress and federal agencies need to adopt and implement policies that ensure AI/ML clinical systems that are safe, accurate, and efficient.

Congress

- Modernize laboratory regulations for AI: Congress, in collaboration with federal agencies, should update existing laboratory laws and regulations (such as CLIA) to explicitly encompass AI/ML systems.
    - Modernization should be risk-based and leverage current laboratory quality management systems instead of creating new, duplicative oversight structures. This approach will safeguard patient safety without stifling innovation in AI.

Federal Agencies

- Establish AI validation and verification standards: Federal health agencies, in partnership with professional societies, should convene expert clinical laboratorians and informatics professionals to develop consensus guidelines for validating and verifying AI tools in laboratory medicine.
- Advance harmonization of laboratory data: Federal stakeholders (such as the CDC, FDA, NIH, and others) should expand and support initiatives to harmonize laboratory test results and standardize data reporting, which will improve the consistency of the data that AI systems rely on.
- Clarify stakeholder roles and responsibilities: Federal health authorities should issue guidance that clearly delineates the responsibilities of each stakeholder involved in developing and deploying AI in laboratory medicine.

Healthcare Community / Clinical Laboratories

- Require continuous performance monitoring: Clinical laboratories and other healthcare organizations using AI/ML systems should implement ongoing performance monitoring, analogous to routine quality control and proficiency testing for laboratory assays.

Developers and Vendors

- Ensure access for independent verification: Developers and vendors of AI tools should ensure that clinical laboratories have access to the data and technical resources necessary to independently verify and validate an algorithm's performance.
- Mitigate bias and promote data diversity: AI developers, in coordination with regulators and healthcare organizations, should implement measures to reduce bias in laboratory AI applications.

References

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