February 11, 2026

Department of Health and Human Services
Assistant Secretary for Technology Policy and
The Office of the National Coordinator for Health Information Technology

Subject: HHS Health Sector AI RFI (RIN 0955-AA13)

Dear Sir/Madam:

The Association for Diagnostics & Laboratory Medicine (ADLM) welcomes the opportunity to provide input to the Department of Health and Human Services (HHS) regarding its December 23, 2025 request for information on how to adopt and accelerate the use of artificial intelligence (AI) in clinical care. As the leading association in diagnostic testing and technology, we offer the following suggestions:

Harmonize Clinical Laboratory Test Results to Enable Interoperability

Interoperability refers to the capacity of disparate laboratory and clinical data to be exchanged, understood, and utilized accurately across different care settings. One of the leading barriers to the use of AI within these healthcare settings is the lack of harmonization among laboratory tests. AI systems that use laboratory data often assume that test results are comparable across different testing sites and methods. In practice, this is often not the case. Different testing platforms can produce different numeric results for the same analyte. While each value may be accurate when using a specific measurement system, numeric differences between measurement systems 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.

The lack of harmonized clinical laboratory test results can lead to misdiagnosis, improper treatment decisions, and increase healthcare costs. While Congress has provided the Centers for Disease Control and Prevention (CDC) with $2 million annually since fiscal year (FY) 2018 to work on this issue, this amount is insufficient. ADLM urges HHS to provide additional funding in the FY27 budget to harmonize laboratory test results.

Representative Data to Develop Accurate AI Algorithms for Guiding Patient Care

One of the biggest challenges facing AI is the need to ensure the data used to make healthcare decisions is representative of the population. 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 underestimate 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 an AI model is based on data from one method and environment and then applied in a different setting without adjustment, it may misinterpret results or fail to identify important variations. 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 assay 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 to Ensure Accurate Laboratory Testing

Under the Clinical Laboratory Improvement Amendments (CLIA) regulations, 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 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. Diagnostic applications that rely heavily on laboratory data and lead to decisions with high potential for patient harm should undergo robust validation, ensure transparency, and incorporate continuous monitoring. Lower-risk tools may warrant a more streamlined oversight process consistent with their reduced potential for patient harm.

Improved Test Utilization May Produce Better Patient Outcomes and Reduce Costs

Inappropriate test ordering protocols cost the US healthcare system up to $200 billion annually.[1] The downstream effects of misutilization can be serious for patients and involve missed diagnoses due to missed testing opportunities on one end of the spectrum, and follow-up visits for additional testing or unnecessary treatments that result in serious complications and injuries on the other end. Many providers struggle to stay on top of the best evidence regarding laboratory medicine as test menus grow and become more specialized. Utilizing analytics can help address this growing problem by monitoring test ordering patterns to improve use of guidelines, provide real-time best practice alerts, and automatically cancel duplicative, obsolete and "look-alike" test orders. Analyzing both laboratory and administrative or financial data may uncover hidden utilization patterns and further reduce costs.

ADLM is a global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare. ADLM brings together clinical laboratory professionals, physicians, research scientists, and business leaders from around the world focused on clinical chemistry, molecular diagnostics, mass spectrometry, translational medicine, lab management, and other areas of clinical laboratory science to advance healthcare collaboration, knowledge, expertise, and innovation.

[1] Kaiser Health News. (2017). Unnecessary medical tests, treatments cost $200 billion annually, cause harm. Retrieved October 14, 2020, from https://www.healthcarefinancenews.com/news/unnecessary-medical-tests-treatments-cost-200-billion-annually-cause-harm

We look forward to working with you on this important issue. If you have any questions, please email Vince Stine, PhD, ADLM's Senior Director of Government and Global Affairs, at vstine@myadlm.org, or Evan Fortman, MPA, ADLM's Manager of Government Affairs at efortman@myadlm.org.

Sincerely,

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President, ADLM