

ANNUAL MEETING

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# NYSCLA

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SEPTEMBER 9-10, 2025



THE NEW YORK STATE CLINICAL LABORATORY ASSOCIATION

## Policy & Advocacy Overview from Washington, D.C.

Susan Van Meter, President  
American Clinical Laboratory Association  
September 10, 2025





## Speaker Disclosure

I have no financial conflicts of interest to disclose

# Agenda

- **ACLA Overview**
- **View from Washington, D.C.**
- **Advocacy Priorities:**
  - **Regulation**
  - **Reimbursement**
  - **Infrastructure & Innovation**
  - **Public Affairs**



# Mission Statement

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**The American Clinical Laboratory Association (ACLA) is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers by advocating for policies that expand access to the highest quality clinical laboratory services, improve patient outcomes, and advance the next generation of personalized care.**

# ACLA Members



# ACLA Associate Members

Associate Members include diagnostic manufacturers, non-profits, consultants, law firms, information technology, billing firms, and others who work with the laboratory industry



# View from Washington, DC

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# Political Environment and Calendar

- **Executive Branch**

- HHS, CMS, CDC
- Political appointees; ongoing reorganization; MAHA

- **White House – Congress**

- Financing
- Policy

- **Political Implications of H.R. 1 “The Big Beautiful Bill”**

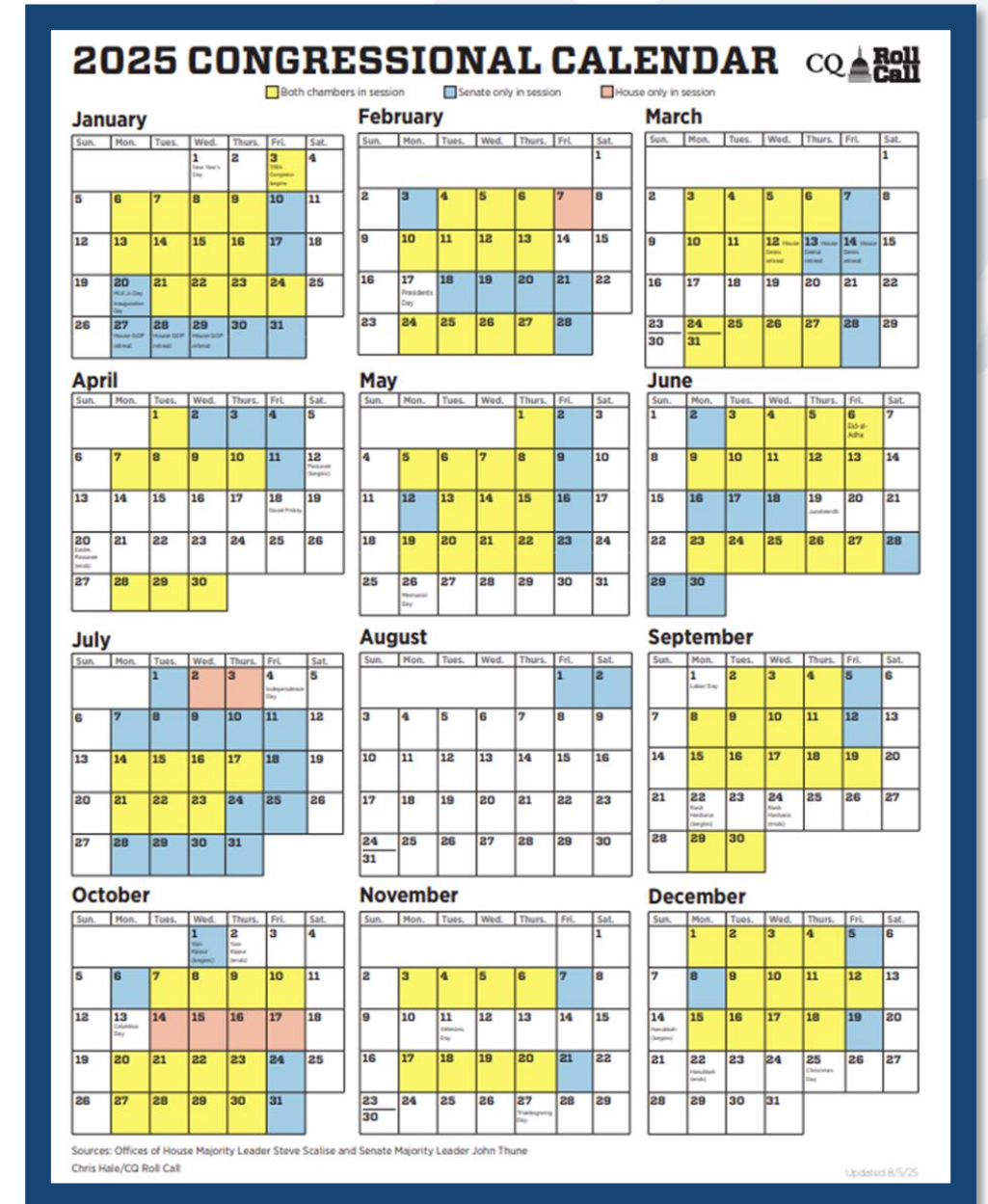
- **Congress**

- FY 25 funding expires 9/30
- FY 26 funding

- **Health Care Extenders**

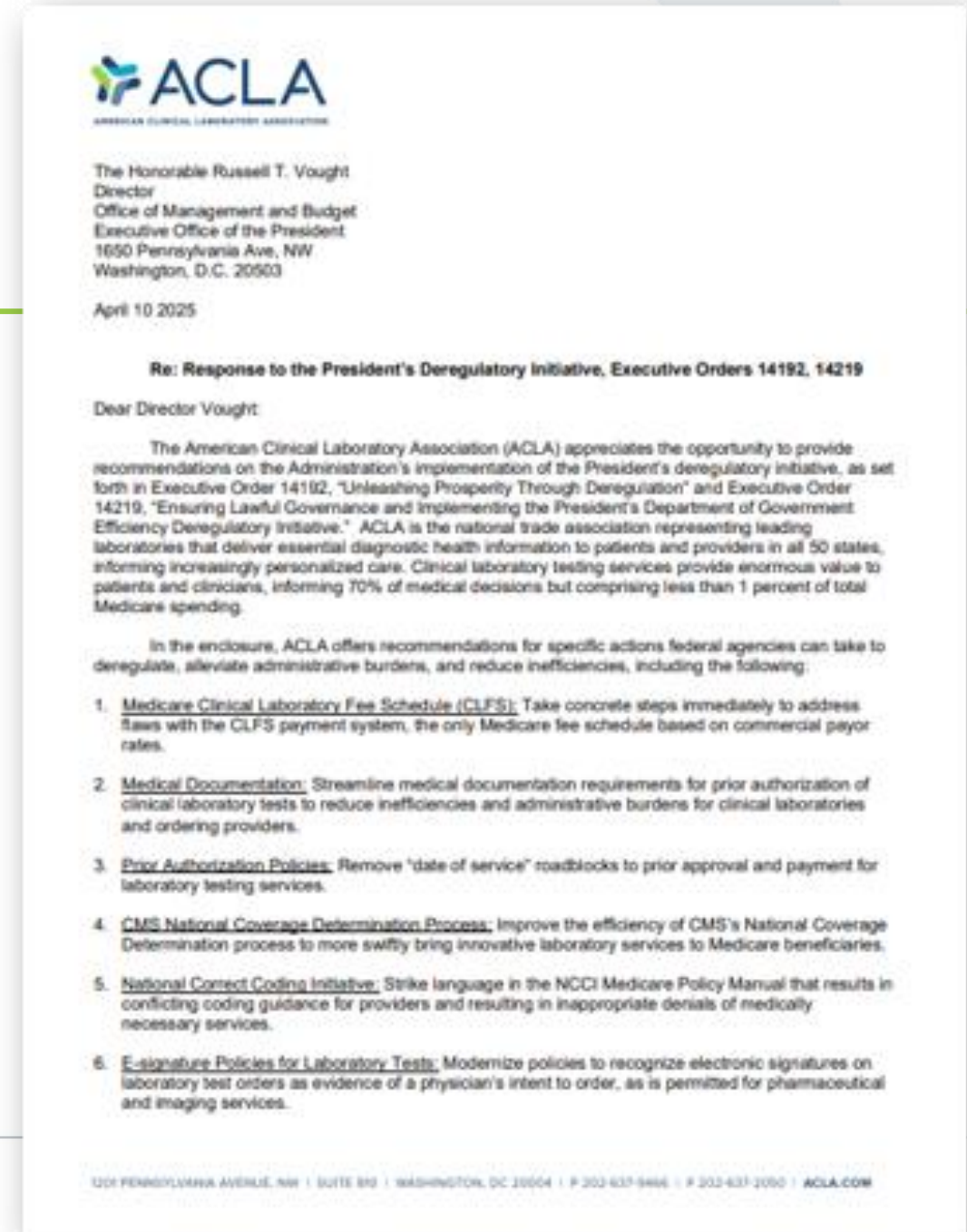
- Some expire 9/30, others 12/30

- **Year-End – PAMA, ACA tax credits, PAYGO**



# ACLA is Leaning-Into The Developing Trump Administration Deregulation Initiative

- The Administration issued its first “deregulatory” Executive Order in March.
- For every 1 new regulation, 10 deregulatory policies must be advanced, including those that would reduce burden on industry and promote innovation.
- ACLA has developed a series of deregulatory policy recommendations rooted in our 2025 priorities agenda.
- ACLA is advancing our recommendations by:
  - Engaging directly with officials in the White House Office of Management and Budget (OMB), the U.S. Department of Health and Human Services (HHS), and the Centers for Medicare & Medicaid Services (CMS).



# Regulation

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# ACLA Succeeded in Challenging the FDA LDT Final Rule that Considered All LDTs to be Illegal

- ACLA has long maintained that for FDA to have any authority in regulatory of LDTs, it should be provided by Congress through legislation
- Rational for ACLA's legal challenge
- ACLA prevailed in *ACLA v. FDA* fully vacating the final rule
- FDA to officially rescind rule in compliance with Court decision; no expectation for new FDA LDT rulemaking

**ACLA will continue to engage with the Administration and Congress on diagnostic policy, prioritizing upholding the value of the *ACLA v. FDA* “win” in any potential legislation or regulatory action**

## FEDERAL COURT VACATES FDA RULE ON LABORATORY DEVELOPED TESTING SERVICES, SIDING WITH ACLA

March 31, 2025 | Categories: [All News](#), [ACLA News](#), [Featured News](#), [ACLA In The News](#), [ACLA Press Releases](#), [Regulatory Issues](#)

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**Washington, D.C.—** The American Clinical Laboratory Association (ACLA) and its member company, [HealthTrackRx](#), today announced a [victory](#) in its legal [challenge](#) to the U.S. Food and Drug Administration's (FDA) Final Rule that would have regulated virtually all laboratory developed testing services as medical devices. The U.S. District Court for the Eastern District of Texas has vacated the Final Rule in its entirety, holding that FDA's attempt to regulate professional laboratory testing services as medical devices exceeds the authority granted to FDA in the *Food, Drug, and Cosmetic Act* (FDCA).

# CLIA: The End of the CLIAC; Expect RFIs from CMS

- In February, an Executive Order required the sunseting of several federal advisory commissions, including the CLIAC
- ACLA is engaging directly with CMS on CLIA policy and
  - Anticipates the release of CMS RFIs to secure laboratory feedback on CLIA policy
  - Urges CMS to establish and hold clinical laboratory open door forum to discuss CLIA policy and policy modernization such as making permanent remote review



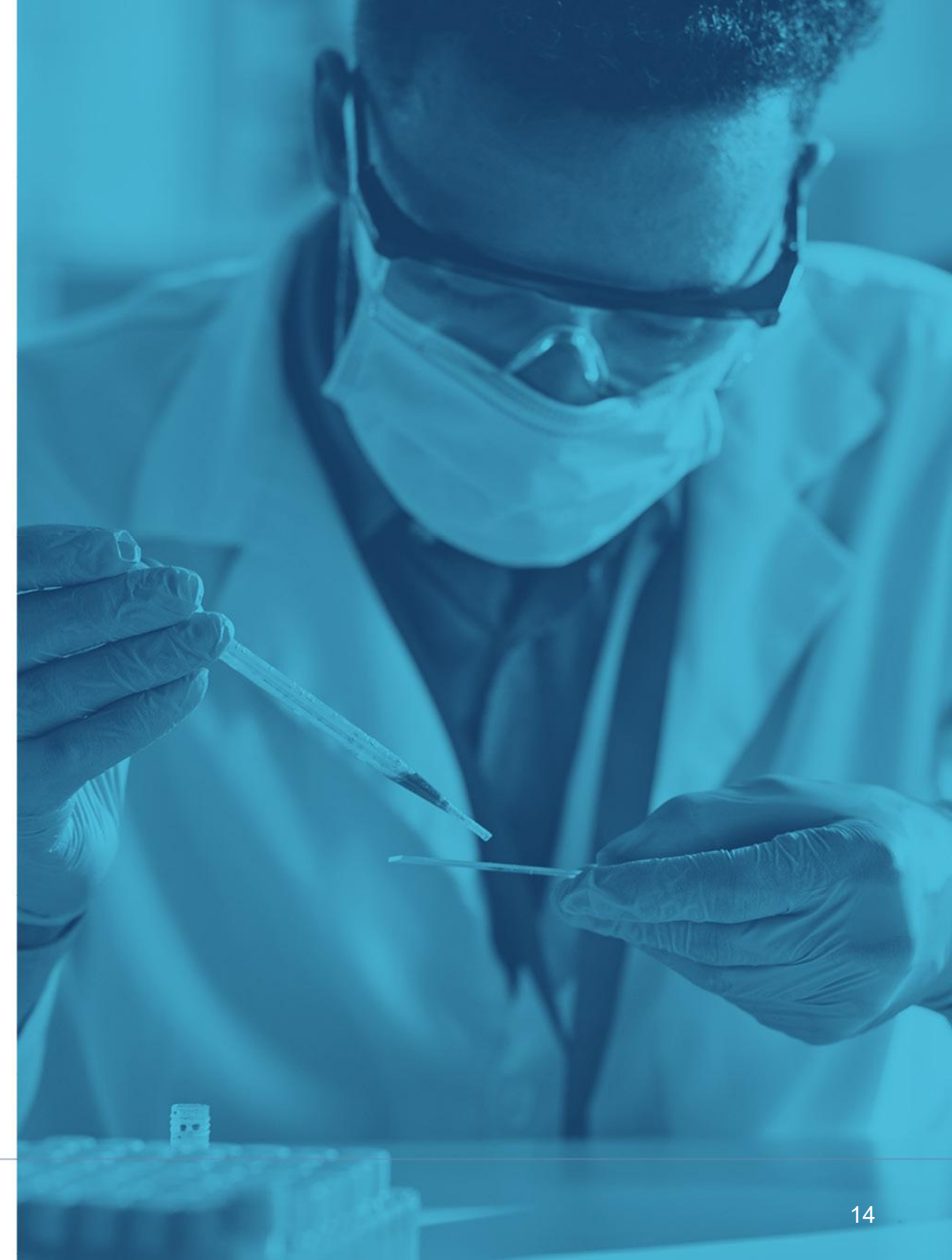
The screenshot shows a CDC website page for 'Federal Advisory Committees (FAC)'. The page features the CDC logo, a search bar, and a navigation menu. The main content area is titled 'Clinical Laboratory Improvement Advisory Committee (CLIAC)'. Below the title, there is a 'For Everyone' badge dated 'JULY 24, 2025'. A prominent orange 'NOTICE' box states: 'Federal laws, regulations, and other applicable HHS policies and procedures are and will be consistently applied to all CDC FACA committees.' Below this, an 'AT A GLANCE' section lists 'Clinical Laboratory Improvement Advisory Committee (CLIAC)'.

# Reimbursement

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## PAMA is Broken

- The Clinical Laboratory Fee Schedule (CLFS), is the only Medicare payment system based on commercial market rates.
- These cuts are a result of flawed implementation of the PAMA. CMS set initial rates based on 2016 data collected from <1% of labs.
- PAMA has resulted in 3 years of up to 10 percent cuts, totaling \$3.8 billion.
- Recognizing the drastic, unintended consequences of PAMA's failed implementation, Congress has stepped in for the last five years to delay additional payment cuts and six years to delay data reporting.
- Cuts of up to 15 percent for 820 tests under the Medicare CLFS are scheduled for January 2026 **if Congress does not act.**
- **The time is now for urgently needed foundational reform to PAMA.**



# The RESULTS Act, Foundational PAMA Reform, Will be Introduced in the U.S. House and U.S. Senate Today

ACLA endorses the RESULTS Act, bipartisan legislation that would improve rate setting in the Medicare Clinical Laboratory Fee Schedule (CLFS), the only Medicare payment system based on commercial market rates. The bill would:

- Reform the Protecting Access to Medicare Act (PAMA) to stabilize the CLFS by dramatically improving the data used to set rates,
- Support and enhance beneficiary access to innovative clinical laboratory services,
- Reduce the administrative burden of data collection and reporting for laboratories and of data the Centers for Medicare and Medicaid Services (CMS), and
- Provide stability to the CLFS and clinical laboratories after years of deep cuts, through improved rate setting and mitigation of future reductions

## RESULTS Act!

(Reforming and Enhancing Sustainable Updates to Laboratory Testing Services)

**STOP LAB CUTS**



### ACLA is grateful to:

House leads Reps Richard Hudson (R-NC), Gus Bilirakis (R-FL), Scott Peters (D-CA), Brian Fitzpatrick (R-PA), and Raja Krishnamoorthi (D-IL), and Senate lead Senator Thom Tillis (R-NC)

# The Benefits of RESULTS:

- **Ensure CMS would have access to comprehensive private payor data representative of hospital outreach, independent, and physician office laboratories**
  - For widely available tests, those for which 100 or more clinical laboratories were paid under the CLFS, or 99.5% of total volume on the CLFS, commercial market data would come from a not-for-profit, independent claims database
  - For non-widely available tests, such as proprietary tests for rare disease, clinical laboratories would report data to CMS
- **Dramatically reduce administrative burden on clinical laboratories and CMS**
- **Set annual “guardrails” to protect against destabilizing decreases in CLFS rates exclude non-market based rates from CLFS rate calculations**
  - Freeze CLFS rates at current 2025 levels, cancelling the pending cuts of up to 15% in 2026.
  - Once fully implemented in 2029, would limit payment reductions to 5 percent per year
- **Extend the frequency of data collection periods from 3 to 4 years**

# Advancing RESULTS on the Hill

- **ACLA seeks any legislative opportunity this fall, including a potential end-of-year, healthcare “extenders” package to advance RESULTS.**
- Join us in our advocacy to secure legislative cosponsors in the House and Senate
- **ACLA’s Stop Lab Cuts** campaign includes:
  - Paid advertising in key states that driver concerned viewers to the StopLabCuts website’s Take Action platform
  - Advocacy tools:
    - Fact Sheet, summaries, videos, social media content
- **As in prior years, ACLA looks forward to working in collaboration with patient, consumer, and other provider organizations to show strong support for PAMA reform now.**
  - In the last Congress over 70 organizations supported PAMA reform.

Seniors deserve to know if they **are at risk for a heart attack.**

**Tell Congress:**  
Protect Access to Medicare  
Lab Tests for Seniors

**TAKE ACTION**

**STOP LAB CUTS**



Seniors deserve to know if they **are at risk of cancer.**

**Tell Congress:**  
Protect Access to Medicare  
Lab Tests for Seniors

**TAKE ACTION**

**STOP LAB CUTS**



## STOP LAB CUTS

Medicare payment cuts threaten patient access to clinical laboratory services, which are essential to preventing and diagnosing diseases and conditions, empowering patients and their clinicians to make informed decisions about care. Tell Congress to pass the Reforming and Enhancing Sustainable Updates to Laboratory Testing Services (RESULTS) Act this year.

TAKE ACTION



### Screening and diagnostic tests performed by clinical laboratories inform life's most important health care decisions.

Scheduled reimbursement cuts under the Protecting Access to Medicare Act (PAMA) could jeopardize access to many of the clinical laboratory tests that are used to screen, diagnose, monitor, and manage common diseases for all patients, including more than 60 million seniors.

But the threat doesn't stop there. After three rounds of up to 10 percent cuts, planned payment reductions of up to an additional 15 percent in 2026 could weaken the clinical lab infrastructure, making it more difficult to deliver routine health care and respond to the next public health crisis.



Since PAMA's enactment  
**72% of tests**  
on the Clinical Laboratory  
Fee Schedule have faced  
payment cuts

## TAKE ACTION

Tell Congress to stop Medicare cuts to clinical laboratory testing.

Send an email to your officials with one click!

Title \*

Full Name \*

Address \*

Zip \*  city and state not required

Phone

Email \*

 Send Email

As your constituent, I urge you to protect patient access to essential clinical laboratory services by fixing the broken payment system for clinical laboratory testing. I am deeply concerned that Medicare payment cuts, scheduled to resume January 1, 2026, could jeopardize access to many essential laboratory tests that are used to diagnose, monitor, prevent, and manage common diseases for 60 million seniors.

Sustainable, long-term payment reform would protect access to laboratory tests by setting forth a simple and streamlined approach that stabilizes reimbursement for clinical laboratory services and enables continued investment in diagnostic innovation and clinical laboratory infrastructure essential for public health.

Send me emails about this campaign

Share with Others

[Twitter](#) [Facebook](#)

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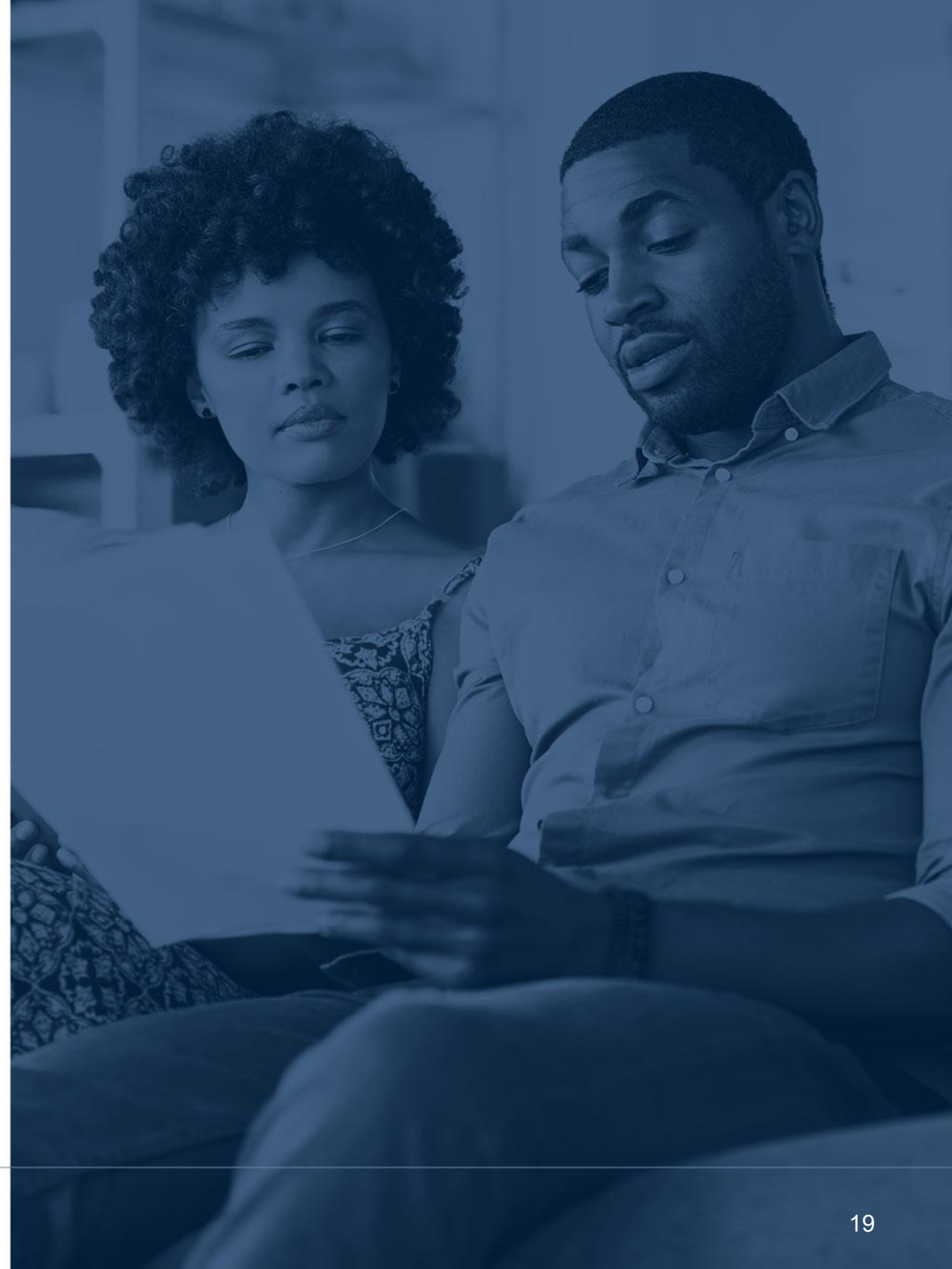
## Stop Lab Cuts Campaign:

- Take Action tool
- Advertising
- Resources

# Coding & Rate Setting

## ACLA Advocacy Focuses on:

- **Securing appropriate coding for new technologies**
  - Robust engagement with AMA on CPT coding
  - Address conflict between AMA coding guidance and that included in the National Correct Coding Initiative (NCCI) Annual Manual and quarterly edit files
- **CLFS Rate Setting:**
  - Collaboration with ACLA members and associate members and other stakeholders to align on recommendations for appropriate rate setting.



# Coverage & Payment

## ACLA Advocacy Focuses on:

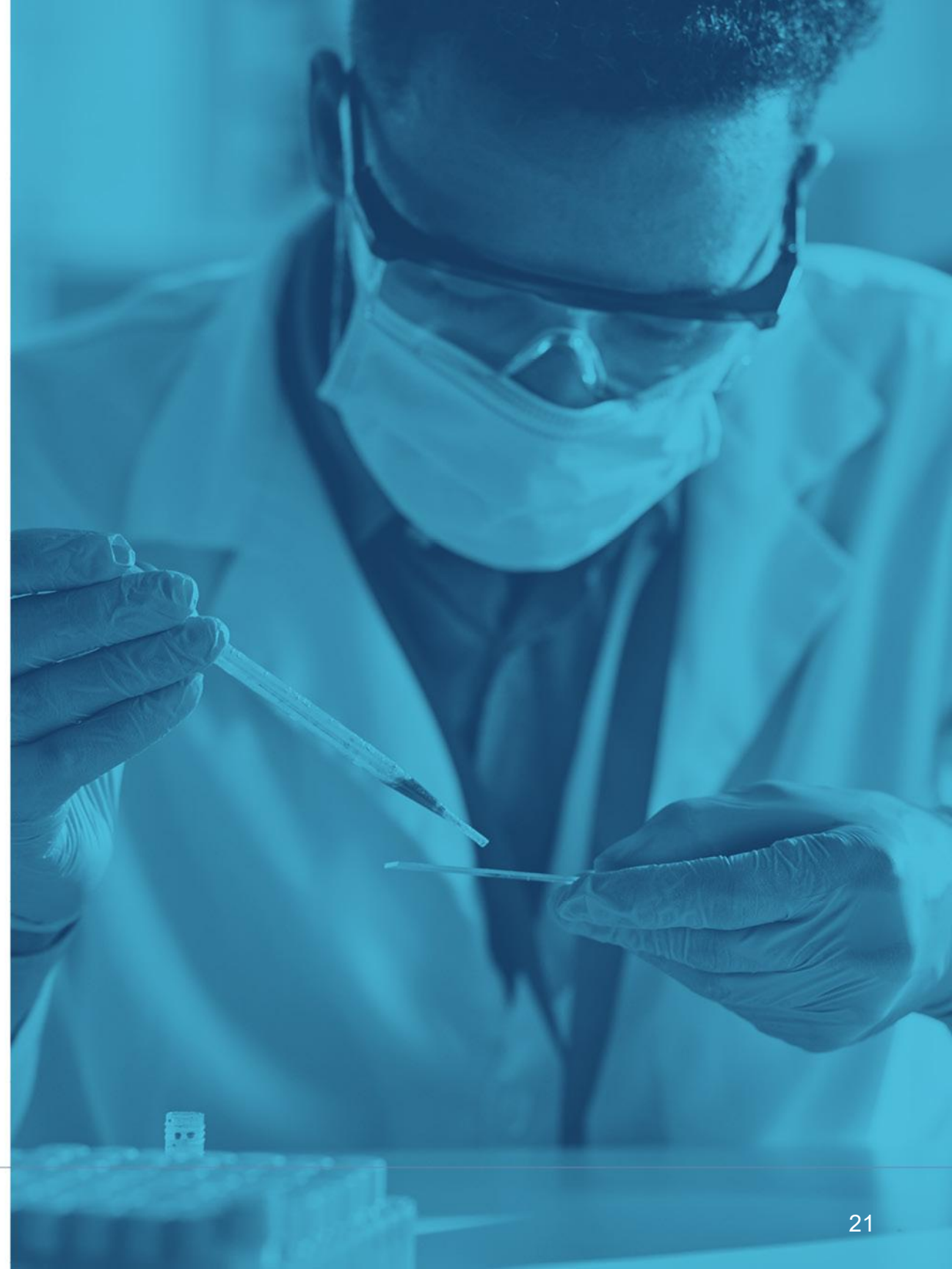
- Public payer policies
  - Local Coverage Determinations by the Medicare Administrative Contractors (MACs)
  - National Coverage Determinations
- Private payer policies
  - All lines of business, including Medicare Advantage
  - Focus on coverage policies and coding requirements
- Public and private payer engagement
  - Prior Authorization and impact of Laboratory Benefit Managers (LBMs)
  - Education on value of diagnostic testing
  - Issues with medical documentation requests and difficulties for labs to supply this information



# Addressing Inappropriate Denials

## ACLA Advocacy to Reduce Overly Complex and Increasingly Burdensome:

- Reducing medical documentation requests
- Improving prior authorization policies to reflect lab workflow
  - CMS's ongoing prior authorization reform
  - Voluntary health plan pledges for reform, and
- Challenging tactics of laboratory benefit managers



# State Biomarker Coverage Law Implementation Advocacy

## States with Biomarker Laws

- AZ
- AR (Commercial Only)
- CA
- CT (Commercial Only)
- CO (Commercial Only)
- FL (Medicaid/state employees only)
- GA
- IL
- IN
- IA
- KY
- LA
- MD
- MN
- NM
- NJ
- NY
- OK
- RI
- TX

## State with Pending Effective Date for Laws

- CT (Medicaid, 1/1/26)
- PA, 1/1/26
- NE, 1/1/28

## ACLA State Issues Forum Advocacy Focus:

### I. Improving State Policy and Process

- ACLA engages with each state that passes a new law, urging robust implementation.
- Recent state level policy advancements include:
  - Expanding Georgia Retro-Prior Authorization Window
  - Establishing Biomarker-Specific Coverage Request Process in California

### II. Improving Model Legislation:

- Work with ACS-CAN to amend model legislation to address implementation challenges
- Secure policy improvements in implemented states

# Preparedness & Innovation

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# Public-Private Partnership is Essential to Robust Preparedness

- **Shifting preparedness landscape in DC**
  - White House Office of Pandemic Preparedness and Response Policy no longer a central driver
  - Significant staff and reorganization changes throughout CDC, FDA, ASPR
  - PAHPA authorization lapsed
- **ACLA maintains MOUs with CDC and private stakeholder partners**

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## Proposal for a national diagnostics action plan for the United States

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<sup>d</sup> Independent Scholar



### ARTICLE INFO

**Keywords:**  
Pandemic preparedness  
Diagnostic testing  
COVID-19 response  
Mpox  
Laboratory testing

### ABSTRACT

Providing a definitive diagnostic test in a disease emergency is critical to limit pathogen spread, develop and deploy medical countermeasures, and mitigate the social and economic harms of a serious epidemic. While major accomplishments have accelerated test development, expanded laboratory testing capacity, and established widespread point-of-care testing, the United States does not have a plan to rapidly respond, to develop, manufacture, deploy, and sustain diagnostic testing at a national scale. To address this gap, we are proposing a **National Diagnostics Action Plan** that describes the steps that are urgently needed to prepare for future infectious disease emergencies, as well as the actions we must take at the first signs of such events. These recommendations require substantial collaboration between the US government (USG) and the private sector to solve a series of challenges now, as well as to prepare for the massive and rapid scale-up of laboratory and point-of-care test development and testing capacity in future emergencies. The recommendations include establishing pre-event contracts; ensuring rapid access to clinical samples; creating a permanent public-private testing coordinating body to allow for rapid information sharing and improved cooperation among the USG, test developers, and clinical laboratories; and accelerating testing rollout at the beginning of an event—and thus, the effective public health management of a disease crisis.

# ACLA's Innovation Advisory Forum Educates Policymakers

- ACLA's Innovation Advisory Forum leverages leading clinical laboratory professionals and clinicians to educate policy makers and guide policy development in areas of clinical laboratory innovation, particularly in artificial intelligence (AI).

**ACLA**  
AMERICAN CLINICAL LABORATORY ASSOCIATION

## Artificial Intelligence in Clinical Laboratories

**About ACLA**  
The American Clinical Laboratory Association (ACLA) represents leading laboratories that deliver diagnostic health information to patients and providers by advocating for policies that expand access to quality clinical laboratory services, improve patient outcomes, and advance the next generation of care.

### Empowering Innovation for Enhanced Patient Care

In clinical laboratories, where precision, efficiency, and quality are paramount, artificial intelligence (AI) including machine learning (ML) models, are emerging as promising tools to help address workforce shortages and manage the increasing demand for healthcare services. AI is one of many ways that ACLA member laboratories are utilizing innovative technology to streamline business processes, prioritize and increase the efficiency of workflows, and synthesize data to reduce employee burnout, all to ensure the highest quality services for patients. The diagnosis and decision-making process is still reliant on the expertise of trained professionals, but AI-generated insights that take into account patient history, diagnostic test results, and medical records may assist clinicians with making a comprehensive diagnosis and formulating a treatment plan.

### Applications of AI in Laboratories

AI has the potential to help laboratorians prioritize and streamline their work to increase efficiency and volume, leading to the ability to serve more patients and develop individualized treatment plans. Developments in laboratory medicine is based on AI's ability to quickly analyze large amounts of data, identify trends, and produce accurate insights that can support clinical decision making. AI also has the potential to improve business operations, streamline workflow, and ease administrative burdens.

Some examples of how ACLA members are utilizing AI include:

- **Data Analysis and Reporting:** AI can synthesize and analyze data in the laboratory information system (LIS) and peer-reviewed research to provide advanced results reporting, including additional recommended testing, potential diagnoses or patient outcomes, or clinical trial opportunities.
- **Digital Pathology:** Digital pathology is the process of digitizing physical glass slides for review by laboratorians and physicians on a computer or mobile device. AI can review slides to flag potentially malignant results, such as tumors and cancer biomarkers, to provide additional review and allow for additional review capacity.
- **Quality Improvements:** AI can help to serve as a quality check to flag discrepancies from review, reducing variability in inter and intra-pathologist interpretation of results to improve standardization of test results.
- **Simplifying Ordering Provider Processes:** Digitizing test ordering and billing processes.

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For more information, visit [www.acla.com](https://www.acla.com)

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March 15, 2025

Faisal D'Souza  
Networking and Information Technology Research and Development  
National Coordination Office  
National Science Foundation  
2415 Eisenhower Avenue  
Alexandria, VA 22314

Submitted electronically

**Re: Development of an Artificial Intelligence (AI) Action Plan**

Dear Mr. D'Souza,

The American Clinical Laboratory Association (ACLA) appreciates the opportunity to respond to the request for information on the Development of an Artificial Intelligence (AI) Action Plan, as directed by President Trump's January 23, 2025 Executive Order 14179 (Removing Barriers to American Leadership in Artificial Intelligence).

ACLA is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers by advocating for policies that expand access to the highest quality clinical laboratory services, improve patient outcomes, and advance the next generation of personalized care. We appreciate the Administration's efforts to curb unnecessarily burdensome requirements that may hamper innovation. These efforts are critical to ACLA's patient-centered mission as well as our shared priorities around promoting a healthier America. As clinical laboratories strive to empower patients with actionable information about their health, AI tools can bolster the ability to detect the onset of diseases and changes in chronic conditions. One such example is transforming women's healthcare by leveraging digital cytology utilizing AI to detect cervical cancer – saving lives, improving care delivery, and ameliorating persistent shortages in the field.

In clinical laboratories, where precision, efficiency, and quality are paramount, AI innovations, including machine learning models, are emerging as promising tools to help address workforce shortages and manage the increasing demand for healthcare services. AI is one of many ways that ACLA member laboratories are utilizing innovative technology to streamline business processes, prioritize and increase the efficiency of workflows, and combine and summarize data from multiple sources to reduce employee burnout, all to ensure the highest quality services for patients. Additionally, while the diagnosis and decision-making process is still determined by the review and expertise of trained healthcare professionals, AI-generated insights that take into account patient history, diagnostic test results, and medical records may assist clinicians with making a comprehensive diagnosis and formulating a

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# Public Affairs: Communicating the Value of Clinical Laboratories

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# Showcasing the Value of Clinical Laboratories

## ACLA's *The Power of Knowing* Campaign

- ACLA's campaign to highlight the foundational nature of clinical laboratories to improving and saving lives.
- Campaign is focused on educating policy makers Inside the Beltway
- Advertising.
- Dissemination of "value facts" on social media.
- Visit: [acla.com/the-power-of-knowing](http://acla.com/the-power-of-knowing)



Because **precise treatment is critical for lung cancer patients, clinicians rely on lab tests** that identify genetic mutations, guiding targeted therapies to improve outcomes.

**THE POWER OF KNOWING.**  
AMERICA'S CLINICAL LABS.



Because our newborn had a **difficult-to-diagnose condition**, our doctor recommended a test that can detect thousands of genetic diseases at once, leading us to a treatment that saved our baby's life.

**THE POWER OF KNOWING.**  
AMERICA'S CLINICAL LABS.



**Thank you**

