ASCLS The American Society for Clinical Laboratory Science MICHIGAN

NEWSLINKS

SUMMER 2025 AMERICAN SOCIETY FOR CLINICAL LABORATORY SCIENCE - MICHIGAN VOLUME 37, NUMBER 3

President's Message

Caitlyn Madden

Thank You

Hello and happy summer everyone! I hope you have all had a chance to enjoy the warm weather, a break from the school year, and all the festivities that summer brings! The new ASCLS-Michigan membership year is upon us, and with that I transition my role on the ASCLS-MI Board of Directors from President to Past President.

Filling the role of both President-Elect and President has been quite the experience. While it was a little daunting to step up into these positions, I am grateful for the opportunity to have served. I'm especially thankful for our other BOD members, both elected and appointed, and the incredible work they have done this past year. As I said in my previous article, one of the great things about serving on the board is that it comes with a built-in support system and I am glad that I had so many people I could turn to for guidance and input. I'm also thankful for our amazing ASCLS-MI members and the support they have given to both myself and ASCLS-MI as a whole. This time was truly a unique and educational experience. I feel as though I have gained a wealth of knowledge as well as grown as both a professional and a leader.

As we come into the new membership year, I look forward to continuing to serve and provide my support to our new president, RJ Benson who began his term on August 1. I also plan to continue to provide support to all of you as well. I welcome anyone to reach out to me whether they have questions about membership, serving on the BOD, or even just reaching out to say hi!

I wish you all a wonderful rest of your summer and a great start to the 2025-2026 ASCLS-Michigan year!

ASCLS MICHIGAN

Thank You

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By K.Farar

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D	B	J	N	W	J	T	F	D	Q	E	C	X	F	L	S	H	Z	Z	W
G	N	I	P	Y	T	O	N	E	H	P	O	N	U	M	M	I	B	J	S
C	S	F	M	A	M	A	T	U	T	G	A	K	Y	H	Z	H	C	V	Y

American Society for Clinical Laboratory Science Michigan

ASCLS-Michigan *Newslinks*

A quarterly publication of the American Society for Clinical Laboratory Science-Michigan. This newsletter is available on our website, distributed via email link to members and posted on the ASCLS-Michigan Facebook page.

Intended Content

Member submissions:
Articles focusing on the medical laboratory profession are encouraged, including case studies, workplace activities, district events, committee reports, technology developments, awards and any other relevant and necessary information.

Non-member submissions: .
Educational Institutions and Commercial Organizations: Sponsors of Annual Meeting will be recognized and may submit materials for approval by ASCLS-Michigan leadership.

Deadlines for articles are the 30th of the months of April, July, October & January. Articles must have name of author. Anonymous letters will not be published. The editor reserves the right to edit all materials submitted for publication. Articles appearing in *Newslinks* represent the opinion of the author and may not represent the opinion of the society.

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Membership: Join ASCLS-Michigan by visiting the ASCLS web site:
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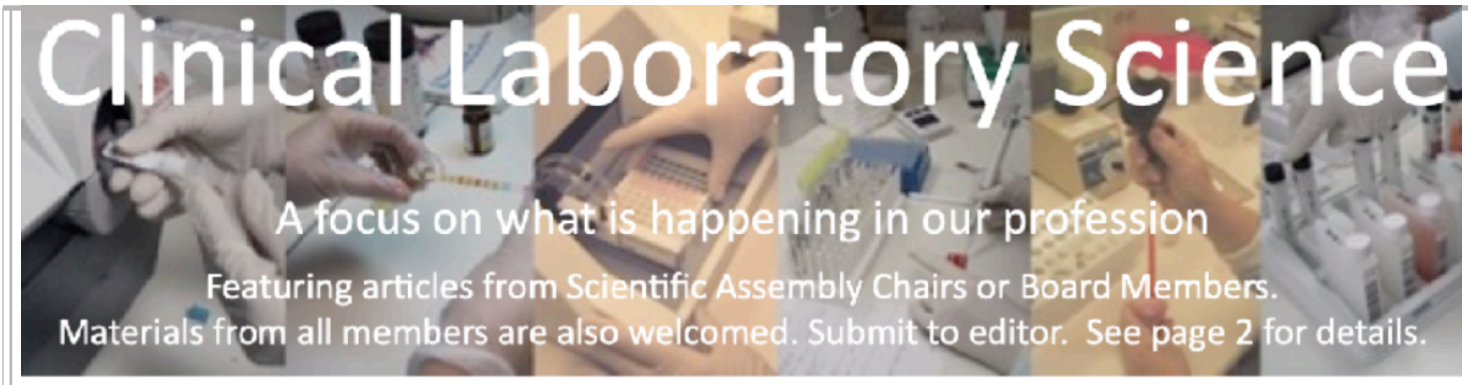
(https://ascls.org/join/)

ASCLS-MI Leadership: Visit our web site at **www.ascls-michigan.org**

for a complete listing and contact information for all ASCLS-MI board members and a wealth of other information on the Society.



Paul Guthrie

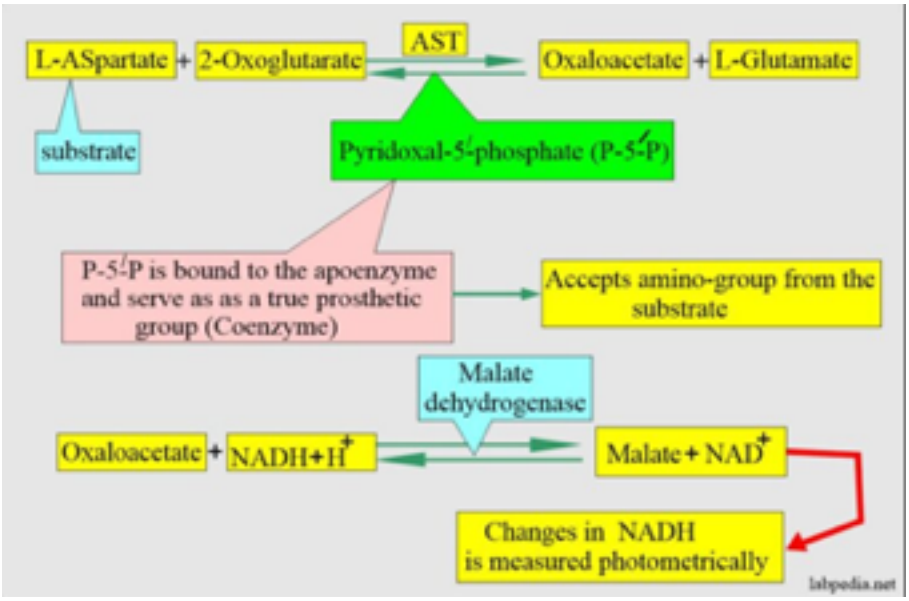
P5P - AST & ALT

How Aware are You and Your Laboratory?

Earlier this year, the laboratory I work in added an additional, new model of analyzer (Roche cobas c503) to our chemistry automation line. This new module uses different reagent kits than the existing modules (c701) in this lab and other system labs (c501/c502). Extensive method validation and patient comparison studies were performed between the old and the new methods, and no significant differences were noted. However, recently we completed an internal twice yearly instrument comparability study as required by the College of American Pathologists (CAP). We elected to use CAP calibration verification materials so that we would cover more of the measuring range than if we used randomly selected de-identified patient samples. Using these materials revealed something we were not aware of; the impact of reagent supplementation with P5P (Pyridoxal-5'-Phosphate) aka Vitamin B6 on Aspartate Transaminase (AST) and Alanine Transaminase (ALT). As shown in the table below from our AST evaluation, the new analyzers recovered up to 30% higher than the old analyzers on samples with significantly elevated values.

Instrument Comparability									**CAP/CLIA PT Limit: +/-15% or 6 U/L** (whichever is greater)					
Specimen	**Test**	**Primary Mean (c701)**	**Line 2 (c701)**	**Line 3 (c503)**	**Line 3-2 (c503)**	**L2 vs Primary**	**L3 vs Primary**	**L3-2 vs Primary**	**CAP Cal Ver Allowable Error**		**Unit**	**L2 Within Range?**	**L3 Within Range?**	**L3-2 Within Range?**
Ln-48	AST	13	14	12	12	1.00	-1.00	-1.00	+/-	5	U/L	Yes	Yes	Yes
Ln-49	AST	180	174	194	197	-3.45%	8.05%	9.77%	+/-	12.5%	%	Yes	Yes	Yes
Ln-50	AST	342	328	373	382	-4.27%	9.45%	12.20%	+/-	12.5%	%	Yes	Yes	Yes
Ln-51	AST	490	483	551	561	-1.35%	12.73%	14.80%	+/-	12.5%	%	Yes	No	No
Ln-52	AST	654	643	769	778	-1.71%	17.88%	19.28%	+/-	12.5%	%	Yes	No	No
Ln-53	AST	802	767	965	974	-4.50%	21.32%	22.49%	+/-	12.5%	%	Yes	No	No
Ln-54	AST	894	882	1142	1154	-1.30%	28.17%	29.54%	+/-	12.5%	%	Yes	No	No

What was the cause of these discrepancies? A review of the menu of the manufacturer's test menu shows that for the older analyzer models, AST & ALT reagents are available both with and without P5P supplemented reagents, whereas the new analyzer is only available with P5P. Our older analyzers used the without P5P versions. P5P is a catalytic cofactor required for the enzymatic reactions to occur for both AST and ALT. The reaction for AST is diagramed below: [1]



When the reagent is not supplemented with P5P, the extent of the reaction relies on the patient's endogenous vitamin B6 within the blood sample. Therefore, the use of reagents without P5P supplementation may underestimate ALT and AST concentrations in patients with vitamin B6 deficiency and may fail to identify patients with significant acute or chronic liver injury. Another concern is that patients with deficiency who are being monitored, and not tested by the same type of reagent each time could have misleading trends reported. In our most recent instrument comparison study using the CAP Calibration Verification materials, it is likely there was not much endogenous P5P in the samples. In that study we noted that the higher the AST or ALT value, the greater the percent underestimation. Samples in the normal and moderately elevated ranges agreed better. Had we used random patient samples the odds are we would not have selected any with vitamin B6 deficiency and/or significantly elevated transaminase values and missed this. These are the likely reasons the issue did not become apparent in our original method validation comparison studies.

In 2002, the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) published reference measurement procedures for both ALT and AST that specify reagents supplemented with P5P. Yet, many major assay manufacturers continue to provide ALT and AST reagents both with and without P5P supplementation. Why is that? I don't know the reasons for all vendors, but I did find a few differences for our analyzer (Roche c701) between the non vs with P5P. The "with" reagent has a shorter open onboard stability (2 vs 4 weeks), the kit size is smaller (approx. 750 vs 1100 tests) and is not ready to use; a bottle must be opened and poured into the test cartridge before loading the reagent. It may be noted that on the newer analyzer (Roche c503), the stability and kit size equal or surpass the old versions of the non P5P reagents, and the kit is also ready to use.

What is the status of P5P reagent supplementation in our medical laboratory industry? In May 2023, the CAP distributed supplemental questions to clinical laboratories that participated in the General Chemistry and Therapeutic Drugs proficiency testing program (C-B 2023). The objective was to assess awareness and adoption of P5P supplementation in ALT and AST assay reagents. They published the findings in May of this year[2]. Of 4,304 laboratories responding only 38.4% report using P5P supplemented reagents. A very interesting observation in this survey was the large

percentage of respondents who said the reason they did not adopt P5P reagents was it was not available from the vendor, in spite of the fact that "with P5P" was available. The study concluded "Overall, the results highlight the degree of variation of ALT and AST method approaches and a general lack of awareness of the existence and benefits of P5P-supplemented ALT and AST reagents."

Reported ALT Reagent Codes Compared with Laboratory Responses and Manufacturer Indications of Availability of P5P Reagent Supplementation [2] (Excerpt from table #4 showing methods our lab uses)

ALT Reagent Group	Laboratories Reporting Not Using an ALT and/or AST Reagent Supplemented with P5P, % (Counts)	Laboratories Reporting P5P Adoption Barrier as "Our Assay Manufacturer Does Not Provide" % (Counts)	Manufacturer or Package Insert Indicates P5P Supplementation is Available for This Reagent
Roche w/o P5P	80.2% (627/782)	48.6% (237/488)	Yes
Roche with P5P	6.9% (15/217)	50.0% (4/8)	Yes

The study also provided three recommendations

1. Review ALT and AST reagent options with their assay manufacturer.
2. Ensure that they are using reference intervals aligned to their specific reagent and patient population.
3. Confirm that they are using the appropriate ALT and AST reagent codes when submitting proficiency testing results.

In reviewing a recent CAP Calibration Verification survey [3] we found that CAP was not able to evaluate the survey for any of the c500 series analyzers in the industry due to "a bimodal/questionable distribution". We suspect this is due to labs not using the appropriate reagent codes in the Cal Ver survey. The new c503 that only offers "with P5P" reagent is replacing the older c501 and c502 in many labs. Most of those older analyzers use "without P5P". Laboratories who changed to the new analyzer kept the old code likely account for the bimodal distribution. The excerpt from the Participant Summary for this survey also shows the c700 series which was able to be evaluated, and demonstrates the under measurement at higher AST levels on the "without P5P reagents.

AST U/L Instrument/Method Instrument Group	N	LN-21 Mean	LN-22 Mean	LN-23 Mean	LN-24 Mean	LN-25 Mean	LN-26 Mean	LN-27 Mean
Roche Cobas c500 series								
w/o P5P	175	*	*	*	*	*	*	*
with P5P	125	12	202	387	575	789	984	1180
Roche Cobas C700 series								
w/o P5P	56	12	184	345	506	658	798	941
with P5P	16	12	209	406	608	780	977	1159

* Due to a bimodal/questionable distribution, the specimens for this peer group cannot be evaluated

In conclusion, now that we are aware, we are working to standardize all analyzers in our system to the "with P5P" reagents. This article was written in hopes of raising awareness for other laboratorians too.

References

1. Graphic from Labpedia.net SGOT-biochemical-reaction-1-1-768x508.jpg (768×508) https://labpedia.net/wp-content/uploads/2020/01/SGOT-biochemical-reaction-1-1-768x508.jpg
2. Arch Pathol Lab Med—Vol 149, May 2025 "Reported Awareness and Use of Pyridoxal-50-Phosphate Supplementation in Alanine Aminotransferase and Aspartate Aminotransferase Assay Reagents, A Survey by the College of American Pathologists Clinical Chemistry Committee, Allison B. Chambliss, PhD; Rhona J. Souers, MS; Jonathan R. Genzen, MD, PhD; David M. Manthei, MD, Ph D
3. Excerpt from College of American Pathologist, Chemistry/Lipid/Enzyme Calibration Verification/Linearity LN2/LN2BV-A 2025 Participant Summary, page 77

Highlights from JAM'25

ASCLS, AGT & SAFMLS Joint Annual Meeting SACRAMENTO 2025

Meighan Sharp was the Joint Annual Meeting Chair. She observed, "As for the meeting itself, I just had a follow up meeting with the chairs of the Annual Meeting Steering Committee. I can say that the meeting was an overall success despite having lower attendance compared to year's past. It was great seeing ASCLS Michigan represented well with me as chair, and Peter Davis and Rachel Morris as speakers. Peter presentation was titled, "Excel-erate Your Lab: Boosting Workflow Efficiency with Digital Tools". Rachel's was, "We Need to Talk: Communicating Science to the Public". Both did a fantastic job, and both received rave reviews.

JAM Attendees

At right: Meighan Sharp, RJ Benson and Suzanne Butch (L-R)

At left: Kristin Landis-Piwowar and Roslyn McQueen (L-R)

As for some of the social activities, The JAM 5K had its highest ever participation yet in Sacramento, and the Blood Drive had a full appointment book with turning people away due to capacity limits. I would expect to see these events for next year's JAM in St. Louis."

Several Individuals from Michigan were recognized at JAM:

- Peter Davis, Scientific Research Award for "Panel Pal: Enhancing Antibody Identification in Blood Bank Laboratories". See additional details on next page.
- Kayla Kruk, CLEF Student Paper Award for her case study "A Pediatric Case of Severe Rhabdomyolysis and Acute Kidney Injury with an Inconclusive Etiology"
- Dale Telgenhoff was part of a group (along with Sally Lewis and Brooke Dubansky) who received a CLS Journal Distinguished Author Award for their Focus article "Molecular Characterization of Colorectal Cancers"
- Morgan Parker, Undergraduate Alpha Mu Tau Scholarship
- Marlena Pinelli, Undergraduate Alpha Mu Tau Scholarship
- Edward Sierras, Golden Service Award for 50 Years of Membership
- Sally Brinkman, Golden Service Award for 50 Years of Membership
- Darby Naheedy, Board Recognition Award for exemplary service on the Elections Committee Taskforce

Peter Davis, pictured at right with ASCLS President **Pat Tille**, received the Scientific Research Award at the 2025 ASCLS Joint Annual Meeting. The award was for his development of a cloud-based antibody identification tool for Blood Bank Panels.

From Peter's post on ASCLS Community:

Dear ASCLS Community,

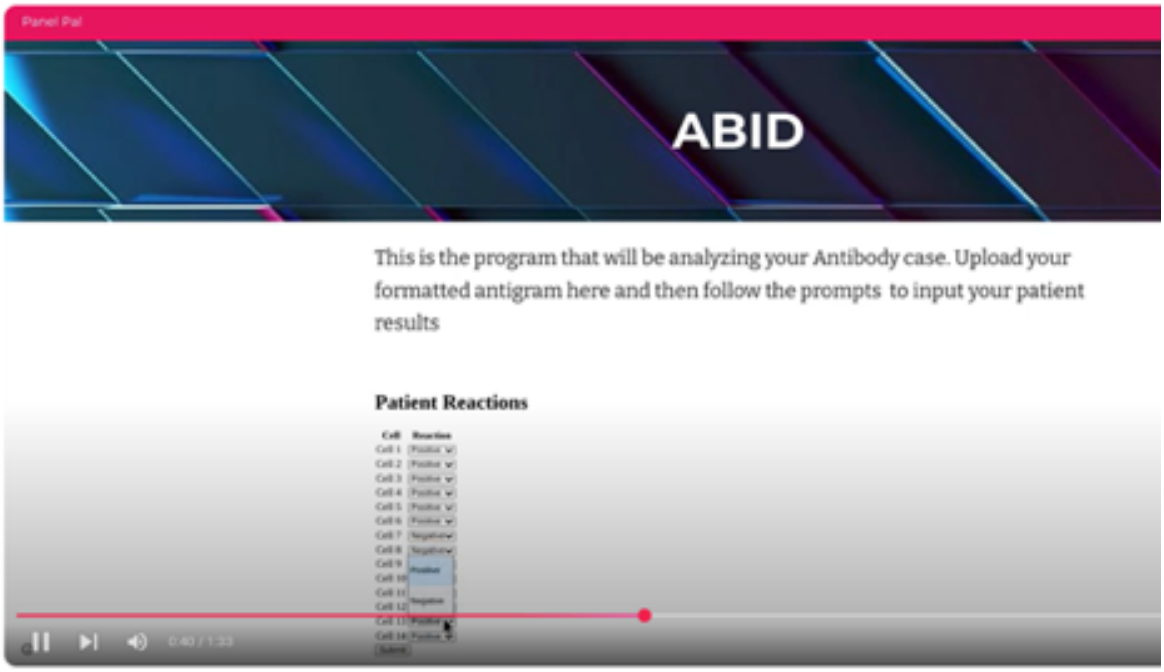
Hi there! My name is Peter Davis, and I'm a Medical Laboratory Scientist passionate about making our work a little easier and smarter. Over the past year, I've been working on something that started as a personal project and quickly grew into something much bigger: Panel Pal, a cloud-based, vendor-agnostic antibody identification tool built specifically for laboratorians.

Panel Pal is designed to support us, not replace us, by offering quick, probabilistic interpretations based on patient panel results. It is compatible with any panel vendor and testing phase, and you can access it from anywhere, even during a night shift when things tend to get interesting. Now that the framework is in place and initial testing looks promising, I hope to invite laboratorians like you to beta-test the tool, share your feedback, and help steer the direction of the next phase. Here's what Panel Pal offers:

- No installation – just open and go
- Compatible with all vendor panels
- Designed for ease of use and clarityBuilt by a fellow tech who knows the 2 a.m. antibody struggle

I'm also excited to share that I'll be presenting the initial research behind Panel Pal at this year's ASCLS JAM conference! Your feedback could help shape what's showcased-and, ultimately, what gets built next.

You can watch an overview of the tool at How to run Panel Pal. Congratulations Peter. Nice work



How to run Panel Pal

ASCLS Responds to Trump Administration Termination of CLIAC

A Centers for Disease Control and Prevention (CDC) spokesperson recently confirmed the Clinical Laboratory Improvement Advisory Committee (CLIAC) was terminated on March 31, 2025, by Donald Trump in accordance with his Executive Order 14217, "Federal Register :: Commencing the Reduction of the Federal Bureaucracy". This was reported on May 29,2025 by G2 Intelligence.

Since then, ASCLS has joined the Association of Public Health Laboratories (APHL), the College of American Pathologists, the Association of Diagnostic Laboratory Medicine (ADLM), the American Society for Clinical Pathology, and many other laboratory science organizations in sending letters to Robert F. Kennedy, Jr. Secretary of the Department of Health and Human Services urging the reinstatement of the Clinical Laboratory Improvement Advisory Committee (CLIAC). The letters may be reviewed at the following links:

2025 CLIAC sign-on letter

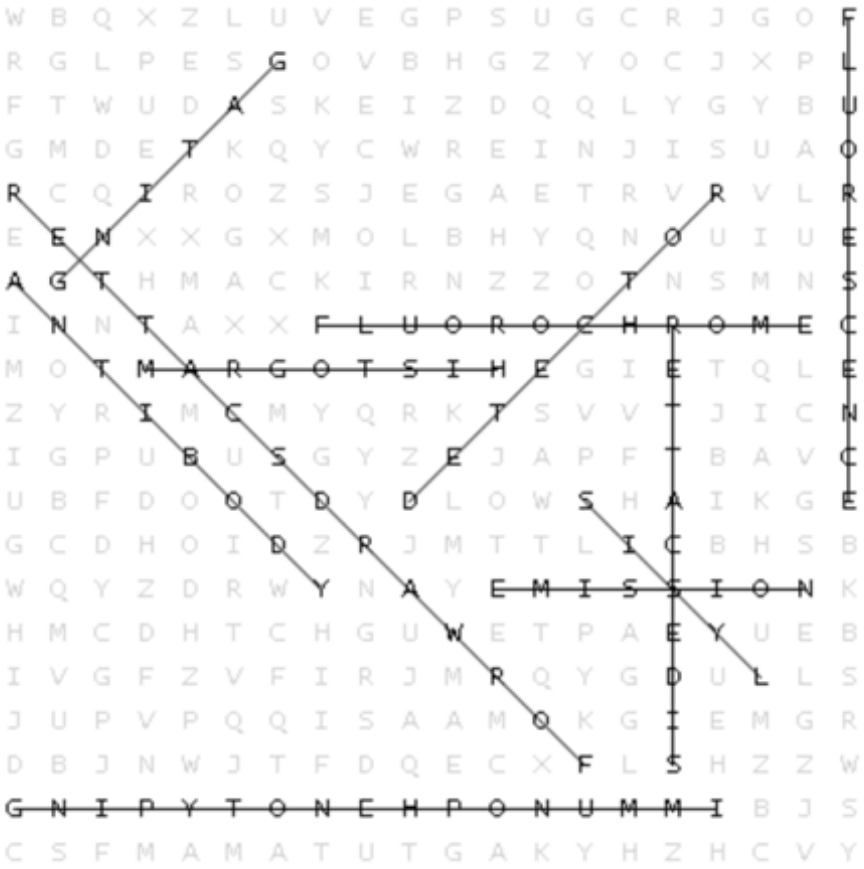
ADLM Urges HHS to Reinstate CLIAC Advisory Committee | myadlm.org

ASCP Urges Trump Administration to Reinstate CLIAC

A few of the points noted in these letters:

- CLIAC was formed in 1992. It served as a forum where federal agencies, in vitro diagnostic companies, professional groups representing laboratory medicine experts, and patients could discuss and find solutions to pressing issues related to the oversight of clinical laboratories.
- The CLIA program, of which CLIAC is a part of, is funded by $80 million in user fees collected from the laboratory community. These funds are spent on educating clinical laboratories about best practices, managing the quality assurance and accreditation programs, conducting inspections, and funding CLIAC. Eliminating CLIAC will have negligible cost savings.
- CLIAC offers expert recommendations to federal agencies on lab regulations.
- Without it, lab regulations risk becoming outdated and disconnected with current laboratory practice.
- Eliminating CLIAC could weaken the health care system and compromise quality of testing.

Key from page 2



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