



COLLEGE of AMERICAN
PATHOLOGISTS
Laboratory Quality Solutions

Your path to laboratory excellence

Get more from your accreditation experience
and see the quality difference.



ACCREDITATION PROGRAMS



Clinical laboratory services play a vital role in helping hospitals and health care systems deliver the highest quality of patient care possible.

Although estimates vary by clinical condition and practice pattern, 60% to 70% of clinical decisions are based on objective data generated through clinical laboratory tests.¹

¹Institute of Medicine. *To Err Is Human: Building a Safer Health System*. The National Academies Press. November 1, 1999; Forsman RW. *Clin Chem*. 1996;42:813–816.

Your path to laboratory excellence is here

Achieving and maintaining laboratory accreditation is a vital part of providing high-quality patient care, but one accreditation body's approach to accreditation and the subsequent benefits it offers can vary significantly from another's. The accreditation experience can be:

- Simply a matter of going through the process and checking off the requirements; or
- An opportunity to learn and grow in the pursuit of continuous improvement for the betterment of patient care.

We find *our* laboratories—those committed to quality improvement that goes *beyond* simply satisfying regulatory requirements—prefer the latter.



Quality that comes from experience



Learning and growing for the patients we serve—that's what makes the CAP the accreditor of choice for >8,000 laboratories in >50 countries around the world.

For laboratory professionals, the CAP's accreditation programs, as well as our specialty accreditation programs, offer the most rigorous choice to achieve and maintain regulatory compliance. The program's peer-inspection model, combined with annual checklist updates and year-round education, provides professional development opportunities to strengthen each laboratory's ability to deliver high-quality service to ensure the best patient care possible.

A collaborative approach

The CAP's accreditation programs are unlike any other. They provide an engaging, dynamic, collaborative process that fosters an environment of continuous improvement. It's more than making the accreditation less stressful—it's learning about emerging best practices across every aspect of laboratory services and finding ways to apply those learnings to improve your laboratory's performance in every area.

Built on more than half a century of experience

Long before the US Clinical Laboratory Improvement Amendments of 1988 (CLIA) were adopted to ensure quality laboratory testing in the United States, the CAP was collaborating with clinicians and medical societies to develop pathology standards and guidelines to improve patient care and outcomes. The CAP's long-term goal was to help physician teams make more informed decisions about diagnosis, optimal treatment, and cost efficiency.

Our comprehensive program incorporates all of the required standards from CLIA, US Food and Drug Administration (FDA), and the US Occupational Safety and Health Administration (OSHA). We also commonly exceed the standards where doing so materially adds to patient care and safety. The CAP retains deemed status (and has for decades) with the US Centers for Medicare & Medicaid Services (CMS), the Joint Commission, the United Network for Organ Sharing (UNOS), the National Marrow Donor Program (NMDP), and many US state agencies.

But the real strength of our accreditation program comes from staying current with changes on the front lines of laboratory medicine and technology through the input of our pathologist members and laboratory professionals around the world. As new advances in medicine and technology emerge and become an accepted part of the modern laboratory workflow, we update our program to reflect the latest best practices. No other accreditor can leverage this kind of working knowledge to keep pace with the evolving laboratory today.

Preferred by top-ranked hospitals

The CAP accredits more than 8,000 laboratories, principally in the US, but also in more than 50 countries worldwide. In the US, most top-ranked hospitals choose the CAP.



US News and World Report Best Hospitals, 2017–2018 ¹	19 of 20	95%
Truven Health Analytics 100 Top Hospitals ²		
2017, Major Teaching Hospitals (≥400 Beds)	15 of 15	100%
2017, Teaching Hospitals (≥200 Beds)	25 of 25	100%
2017, Large Community Hospitals (≥250 Beds)	20 of 20	100%
2017, Medium Community Hospitals (100–249 Beds)	19 of 20	95%
2017, Small Community Hospitals (25–99 Beds)	17 of 20	85%

¹ US News and World Report. US News Best Hospitals web page, accessed June 2018.

² Truven Health Analytics. 100 Top Hospitals web page, accessed January, 2018.

Power of peer review



The CAP's Laboratory Accreditation Program is built on a unique, reciprocal, peer-based inspection method that benefits both the laboratories being inspected and the laboratories providing the inspection teams. Our inspection teams are trained, practicing laboratory professionals who understand the workflows and challenges you face because they face them every day as well. The CAP's inspections are conducted efficiently and thoroughly in a spirit of collaboration.

> 10,000 laboratory professionals from CAP-accredited laboratories participate on inspection teams each year.

At the same time, the inspection teams have the opportunity to observe and learn from a variety of laboratory environments. It's a chance to stay current, share perspectives, and exchange best practices to ensure patient safety and care.

Inspection teams are chosen to match laboratory size and scope of laboratory services, and specialty inspectors are provided for certain highly complex disciplines, such as molecular pathology, cytogenetics, and next-generation sequencing.

“The inspection team from our last peer inspection was excellent. They not only knew molecular diagnostics forwards and backwards, they worked closely with us to ensure that our laboratory was meeting all the requirements.”

**Owatha Tatum, PhD, MBA,
HCLD/CC(ABB)**
Medical Director
MicroGen Dx

“From the very first time I was an inspector, I found the experience to be challenging, invigorating, and inspiring. But more than that, participating on the inspection team helped me fine-tune my medical technologist skills, and expand my knowledge of laboratory operations.”

Nicole E. Corner, MT(ASCP)
Former Manager, Office of
Compliance Accreditation and
Quality (OCAQ)
Indiana University Health
Pathology Laboratory

“There's a real educational benefit when the [inspection] team is from a comparable institution and they have relevant expertise. Being able to bounce ideas off of them and understand how they deal with certain issues is invaluable.”

Laboratory Director
Academic Medical Center

The importance of proficiency testing

Although all US laboratories are required to enroll in a CMS-approved proficiency testing (PT) program for tests involving regulated analytes, most will also participate in various PT/ External Quality Assessment (EQA) programs for nonregulated and waived analytes as part of a commitment to a comprehensive laboratory quality improvement program.

It is the position of the CAP that all clinical laboratory testing used for the diagnosis, prevention, and assessment of human disease should be subject to quality control and PT.

The CAP believes that no test is so simple and straightforward to perform that erroneous results cannot occur and that no incorrect result is “risk free” or inconsequential with regard to potential harm.



To help laboratories maintain high-quality standards for patients, our accreditation program monitors PT results for 83 CLIA-regulated analytes, plus more than 300 analytes specially chosen by pathologists for their clinical utility and medical relevance.

The roadmap to accreditation ...



Checklists simplify the compliance process

Our 21 discipline-specific checklists outline the steps for smooth accreditation and inspection. These annually updated checklists, developed with input from more than 500 pathologists and other experts, provide a clear roadmap for not only achieving accreditation, but also for running a high-quality laboratory. Written in easy-to-understand language, these checklists include:

- Notes, references, and practical examples to further clarify the requirements and facilitate compliance
- Citations to additional resources for further explanation
- Built-in references for easy access to specific regulations
- Education on best practices

Prior to an inspection, we create a custom checklist specifically for your laboratory based on your exact testing menu, so you and the inspection team both know what's being inspected and so there are no surprises. In addition, the CAP has a team of medical technologists ready to address any questions by phone or email, so you always have access to answers.

True “big-picture” perspective

The CAP inspectors use multiple methods when conducting inspections with the Read, Observe, Ask, Discover (R.O.A.D.) approach. With the CAP's R.O.A.D. approach, inspections go far beyond following samples through the process (also known as the tracer technique), providing greater understanding and more actionable information to help laboratories improve their performance.



Read—Inspectors review a sampling of laboratory documents. This information helps guide the Observe and Ask processes.



Observe—Inspectors examine what laboratory personnel are actually doing. Deviations from documented policies and procedures are noted.



Ask—Open-ended, probing questions from the inspectors help corroborate findings uncovered during the previous steps.



Discover—Inspectors drill down using a variety of techniques, which aid in the understanding of preanalytic, analytic, and postanalytic processes while reviewing multiple requirements simultaneously.

... and a high-quality laboratory

Complimentary educational resources for laboratories and inspection teams

Education is a core component throughout every step of accreditation with the CAP. That's why we offer multiple complimentary resources to help laboratories prepare for and achieve accreditation, and we provide comprehensive training for inspection teams and team leaders to ensure consistency and thoroughness for each inspection.

Focus on Compliance webinars

The rules of compliance are complex and ever-changing. Focus on Compliance webinars help you understand and maintain continuous compliance with the requirements, reducing the stress and work of preparing for your inspection. You'll dive deep into the current state of regulatory requirements and explore best practices that will lead to improved laboratory operations, a smoother accreditation process, and improved patient care.

Fast Focus on Compliance mini-training vignettes

A resource for laboratories and inspectors alike, the Fast Focus on Compliance vignettes help you prepare for future laboratory inspections by using real-world scenarios to gain a clear understanding of the requirements and receive insight into areas that need improvement.

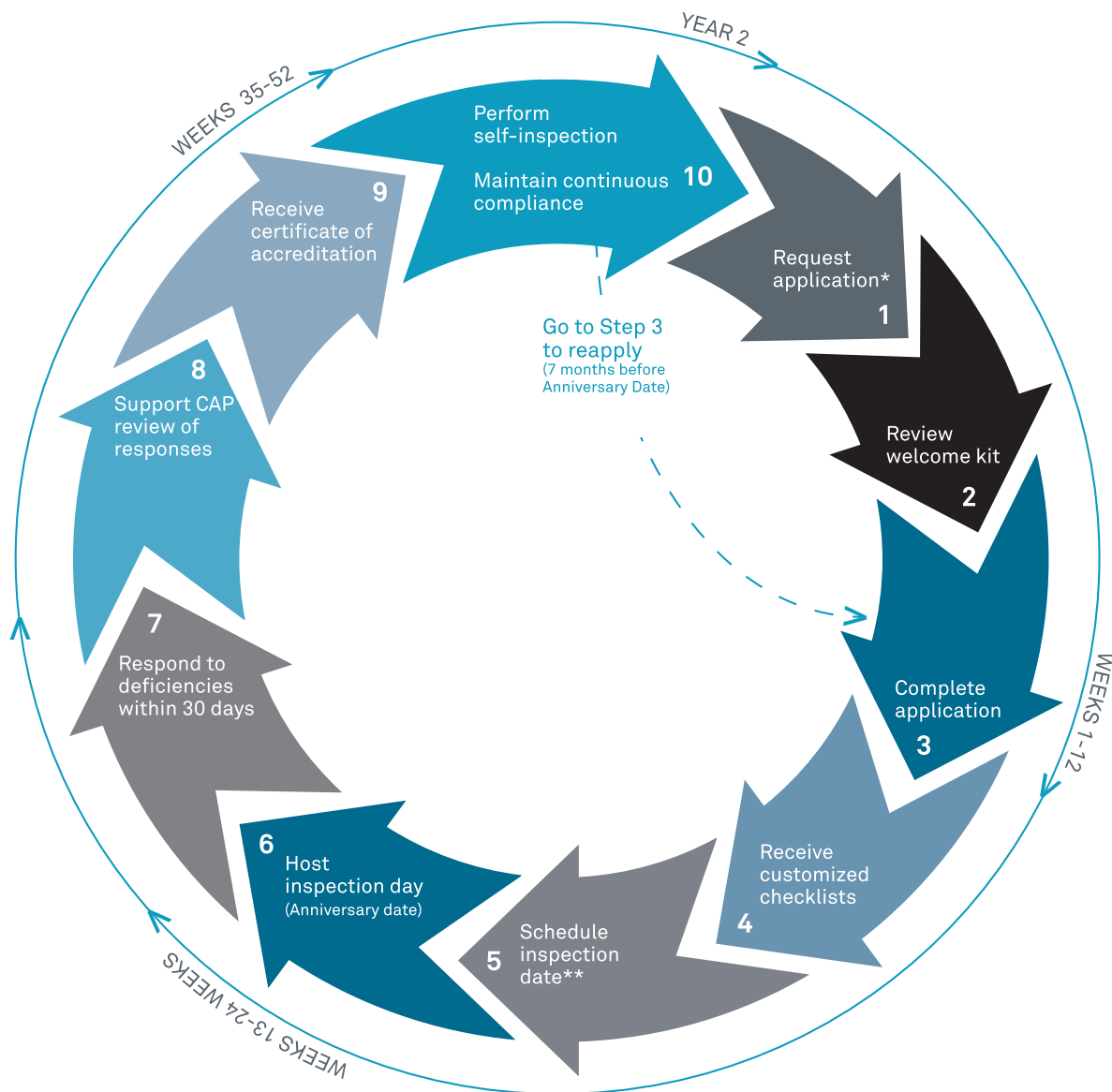
Inspection team training

We also offer complimentary training with continuing education (CE)/continuing medical education (CME)/self-assessment modules (SAM) credit for inspection team leaders and members.

- For team leaders, the course provides the tools and techniques to select appropriate team members and evaluate the laboratory director's involvement in the laboratory's culture of quality and safety as part of the inspection process.
- Team members are provided with inspection or auditing techniques that will assist them in gathering the appropriate information to determine if their findings support compliance with the requirements.



Your continuous cycle for laboratory quality



You can be confident from application to completion as the CAP connects you with experts in laboratory accreditation and provides the tools and guidance needed so you can focus on what matters most—patient care.

* International laboratories must be enrolled in CAP proficiency testing for a minimum of six months before requesting an application.

** The initial inspection is announced for all CAP accreditation programs. Thereafter, all US inspections for the Laboratory Accreditation Program are unannounced (and performed within 90 days preceding the anniversary date) due to the CAP's deemed status with the Joint Commission. Subsequent international and specialty accreditation program inspections are announced.

Specialty and ISO accreditation programs

The CAP also brings its unique and rigorous accreditation model to other areas where high-quality results are needed. Through our specialty accreditation programs, laboratories/facilities that provide reproductive, biorepository, or forensic drug testing services also can benefit from the same peer-based review, annually updated checklists, and year-round education:

Reproductive Laboratory Accreditation Program	Designed for laboratories that perform at least one embryology-related procedure or perform semen analysis and at least one additional high-complexity test. Services accredited include embryology, andrology, cryopreservation, gamete/embryo storage, and limited diagnostic testing (eg, hormone assays, hematology). The CAP's reproductive laboratory accreditation is accepted by the Society for Assisted Reproductive Technologies (SART) to meet membership requirements for in vitro fertilization facilities.
Biorepository Accreditation Program	First accreditation program designed specifically for biorepositories that collect, process, store, and distribute biospecimens. The goal of the program is to provide requirements for standardization in biorepository processes that will result in high-quality specimens that can be used to support research, drug discovery, and personalized medicine. The biorepository checklist is cited as a reference for best practices by the US National Cancer Institute.
Forensic Drug Testing Accreditation Program	Designed for the unique needs of forensic drug testing laboratories and intended for laboratories that perform confirmatory testing on urine, oral fluid, hair, and whole blood and urine screen-only testing by nonwaived methods.

Accreditation to the ISO 15189 Standard

CAP 15189 Accreditation Program	Accreditation to the ISO 15189 standard strengthens the quality management system throughout the laboratory and all parts of the organization that interact with the laboratory, enabling process improvement, risk reduction, and improved operational efficiency. This CAP program uniquely offers an assessment of the maturity of the laboratory's quality management system. Accreditation from the CAP's Laboratory Accreditation Program is a prerequisite. (Available in select markets)
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System inspection option standardizes operations



“When you are responsible for multiple laboratories, standardizing your operations improve your efficiency—and the quality of patient care. The CAP’s system inspection option helps this process. Not only does preparing for the inspection compel you to standardize across sites, the inspection itself quickly identifies areas of nonstandardization. And that makes my job easier.”

Vipul Trivedi, MD

Community Division Chair
Department of Laboratory Medicine
and Pathology
Mayo Clinic Health System

CAP-accredited laboratories with multiple locations that meet specific requirements can arrange for a system inspection where all locations are inspected together by the same inspection team. Benefits of the system inspection option include:

- An assessment of integrated services to promote standardization
- One common version of the CAP accreditation checklists
- One coordinated inspection date/anniversary date for all sites

On the inspection day, a CAP inspection specialist participates in the on-site inspection to facilitate communication and ensure a consistent process. At the end of the system inspection, a post-inspection global summation conference is held with a final report to provide system-level feedback.

Tools and resources to support quality

In addition to the services and resources that are part of the accreditation process, the CAP offers laboratories access to a variety of additional tools and resources to support peak performance.

e-LAB Solutions Suite (ELSS)

The e-LAB Solutions Suite is the CAP's online portal to manage your laboratory improvement programs. In the ELSS, you'll find educational resources such as the PT Toolbox, guidance documents, and tip sheets. The ELSS also makes it easy to manage your laboratory's accreditation documents, including customized accreditation checklists and test menu/activity change forms.

The Performance Analytics Dashboard

Laboratories can manage their risk and compliance with the Performance Analytics Dashboard. Updated daily, the dashboard delivers a single comprehensive view of all your CAP PT results and current accreditation status—right at your fingertips. This complimentary web-based tool will deliver key insights to help you identify and mitigate risk while benchmarking your laboratory's performance.

The CAP Accreditation Readiness Assessment (optional)

The CAP Accreditation Readiness Assessment (CARA) is an on-site evaluation and educational program that shows you how prepared your laboratory is for the CAP's accreditation process. CARA focuses on:

- Facilitating an in-depth understanding of CAP requirements as they apply to your laboratory
- Helping you manage the time and resources necessary for compliance with CAP accreditation requirements and preparation for your initial inspection
- Delivering on-site education when you're ready for it





Choosing an accreditation program can be the difference between just checking the boxes to meet the requirements and opening the door to a world of shared expertise. It's your opportunity to join a team of like-minded professionals who want to drive continuous improvement in laboratory medicine for the betterment of patients.

Only the CAP offers a rigorous, peer-based, and constantly evolving solution for laboratory accreditation. You get support at every step of the process and the unique opportunity to collaborate with other laboratories—as inspectees and inspectors.

See how the CAP's Laboratory Accreditation Program can help you achieve and maintain improved performance on the path to laboratory excellence.

**It's more than accreditation—
it's the opportunity
to be your best.**

Contact us today.



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