



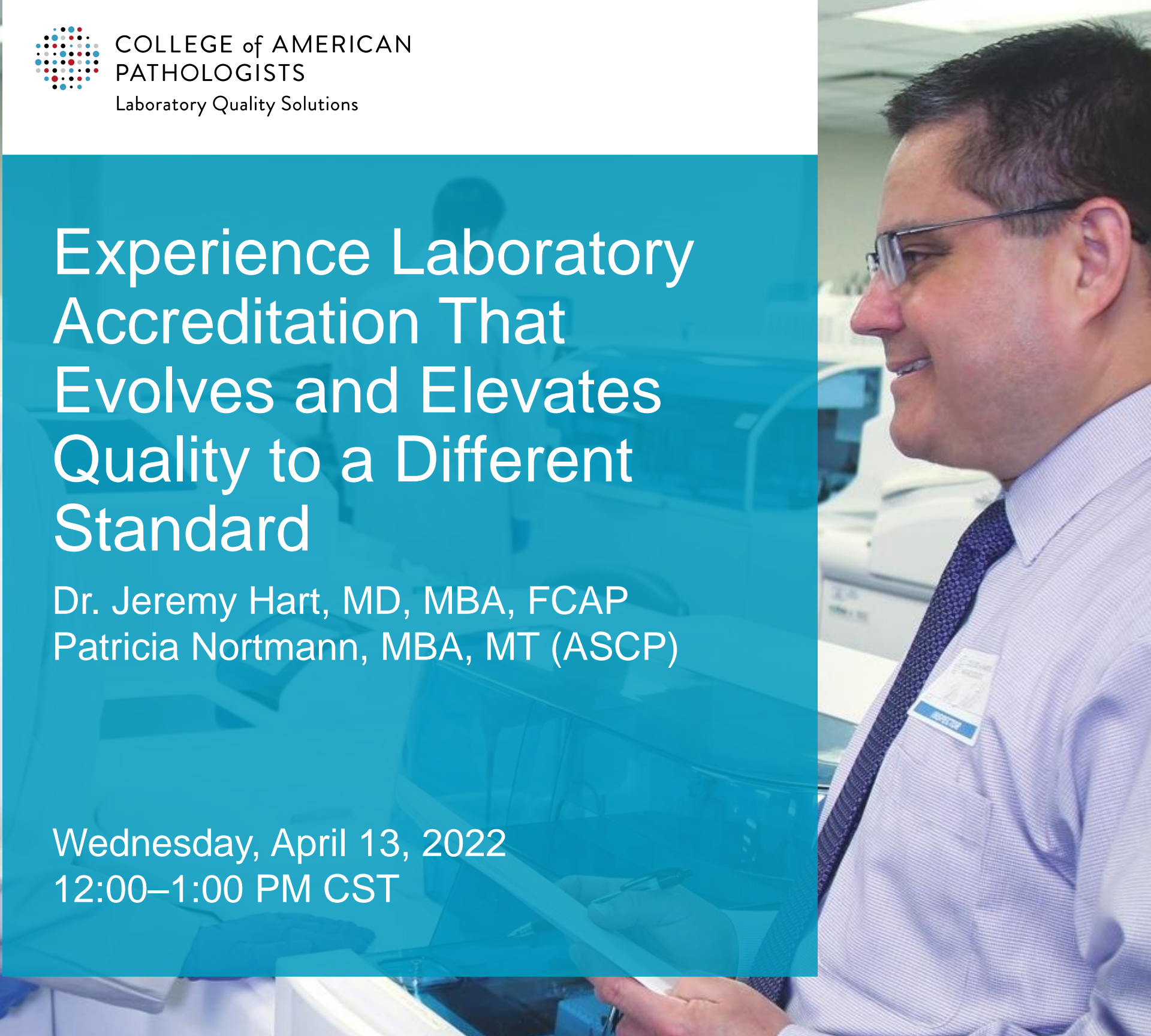
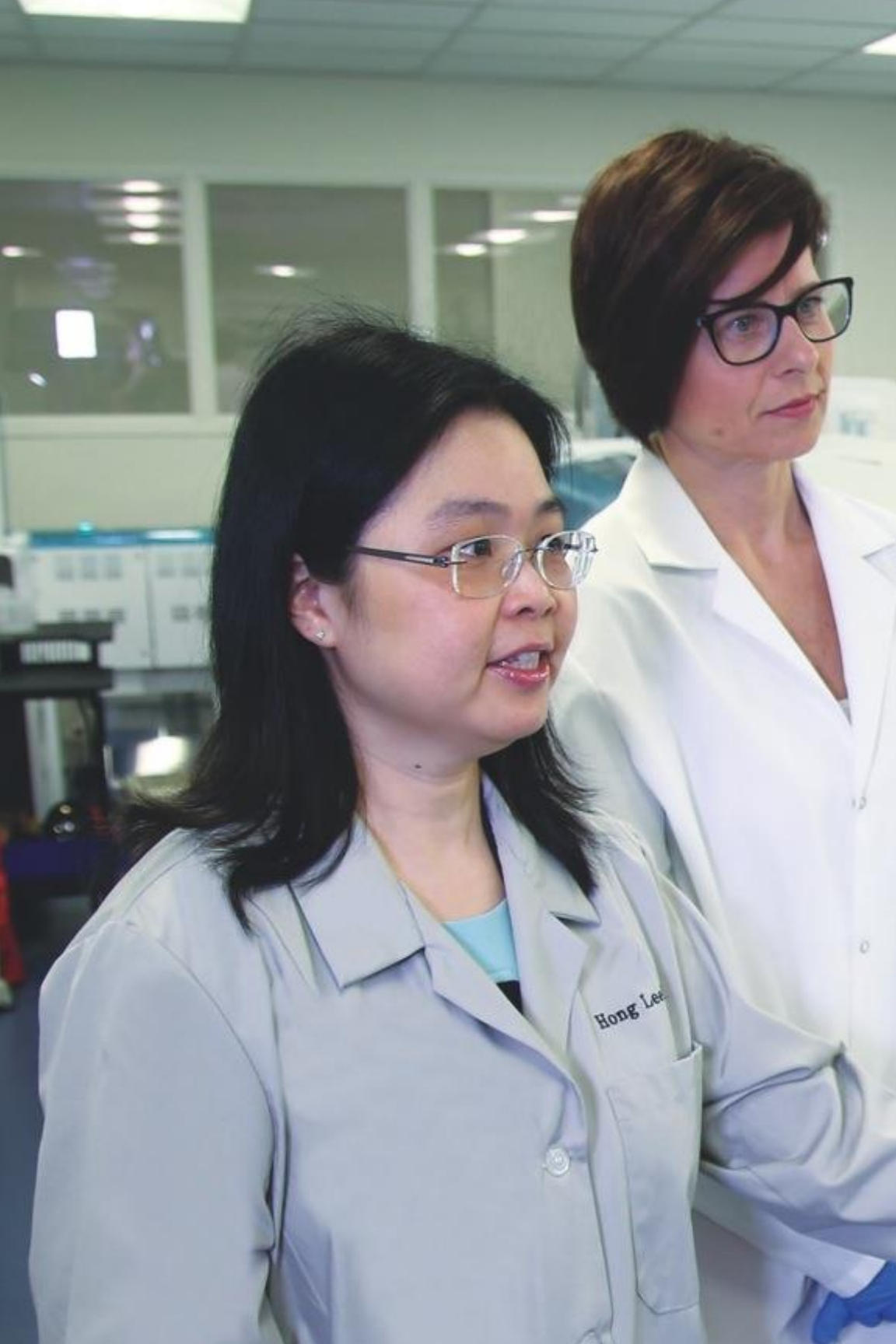
COLLEGE of AMERICAN
PATHOLOGISTS

Laboratory Quality Solutions

Experience Laboratory Accreditation That Evolves and Elevates Quality to a Different Standard

Dr. Jeremy Hart, MD, MBA, FCAP
Patricia Nortmann, MBA, MT (ASCP)

Wednesday, April 13, 2022
12:00–1:00 PM CST



Webinar Housekeeping



Today's webinar
is being
recorded



A link will be
provided so you
can revisit the
content and
share it with
colleagues



We invite you to
interact with the
speakers by
submitting
questions in the
Ask a
Question box



Tell us how we
did in the survey
immediately
following the
webinar

Today's Presenters

Experience Laboratory Accreditation That Evolves and Elevates Quality to a Different Standard



Dr. Jeremy Hart, MD, MBA, FCAP
Medical Director of Clinical Laboratories
St. Elizabeth Healthcare



Patricia Nortmann, MBA, MT (ASCP)
AVP Laboratory Services
St. Elizabeth Healthcare

St. Elizabeth Healthcare

MISSION

As a Catholic healthcare ministry, we provide comprehensive and compassionate care that improves the health of the people we serve.

VISION

St. Elizabeth will lead the communities we serve to become the healthiest in America.

About St. Elizabeth Healthcare

Six facilities throughout
Northern Kentucky &
Southeastern Indiana

Covington

Dearborn

Edgewood

Florence

Ft. Thomas

Grant



165 St. Elizabeth
Physicians specialty and
primary care offices
located throughout

Kentucky

Ohio

Indiana

Laboratories at St. Elizabeth Healthcare

- 10 CLIA certified laboratories
- “System” CAP accreditation
- Joint venture “core” laboratory
- ~\$70 million annual operating budget
- 400+ FTEs and 10 pathologists
- 6.6 million+ annual billable tests
- 19 outpatient draw sites



Operating a High-Quality Laboratory Service at St. Elizabeth Healthcare

Today's Laboratory Needs

Maintain continuous quality improvements to strengthen quality management

Focus on competency, learning, and development

Adapt to an evolving environment while upholding safety for patients and staff



CAP Laboratory Accreditation Program

Customized discipline-specific checklists combined with peer inspections

Access to complimentary learning opportunities, tools, and resources

Annual checklist updates incorporate input from 33 scientific resource committees

The College of American Pathologists

The Preferred Partner for Laboratory Excellence

Focused on Collaboration from Our Founding

- Largest member association of board-certified pathologists
 - ~ 18,000 global members
- Exclusive laboratory focus
- Trusted partner of CMS, FDA, CDC, ASCO, NMDP, UNOS, and many others



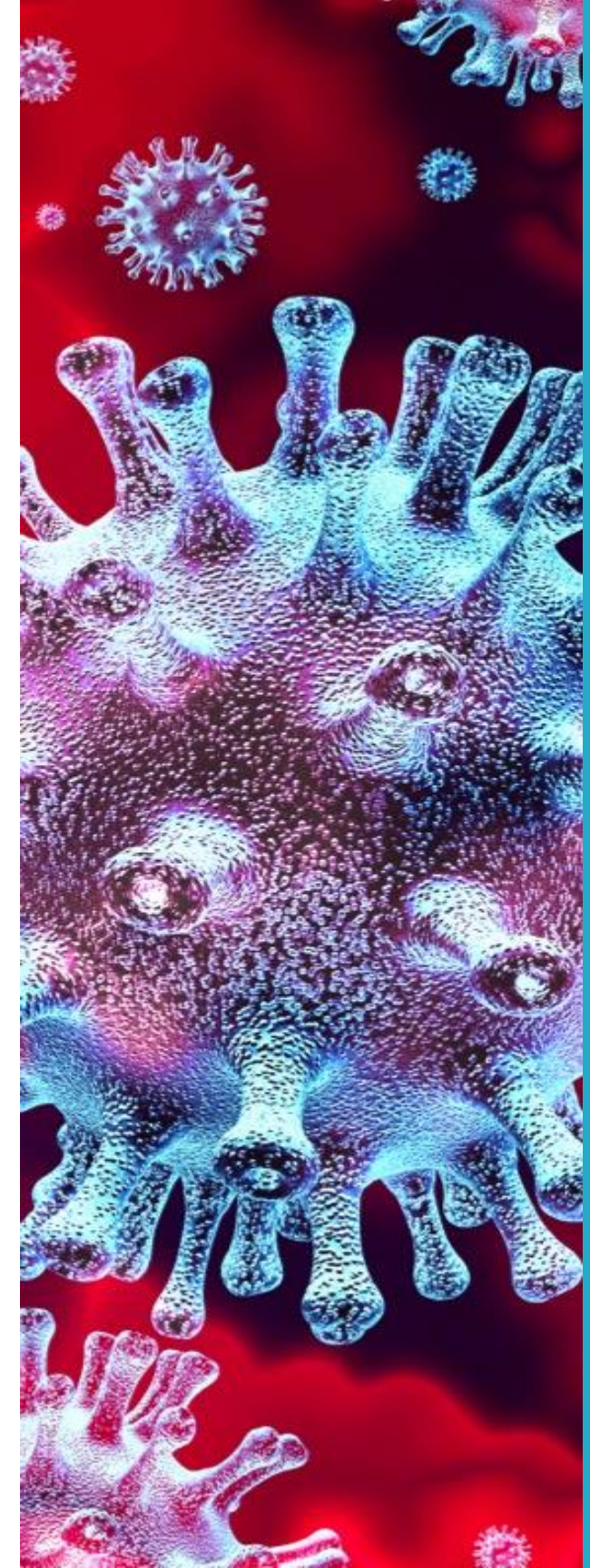
Leading in Laboratory Quality Solutions

- Accrediting nearly **8,000 laboratories** worldwide with **>500** abroad in **50+** countries
- Providing **23,000 laboratories** worldwide with proficiency testing
- Offering **cancer protocols** for complete and accurate diagnostic reports



CAP Leadership in the Pandemic

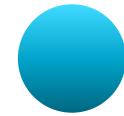
- **Pathologists and laboratorians**
 - Delivered in-depth guidance and tools on implementing SARS-CoV-2 testing in a rapidly evolving environment
- **Laboratory**
 - Launched SARS-CoV-2 proficiency testing for viral and serology tests
 - Successfully petitioned CMS to delay inspections
 - Provided safety precautions for anatomic pathology procedures and autopsies plus recommendations for protecting the blood supply via our resource committees
- **Community**
 - Gave input to the AMA for development of new CPT codes and advocated for increased reimbursement



Accreditation That Goes Beyond Compliance

COMPLY

with CLIA, FDA, and
OSHA standards



EXCEED

>40% of our standards exceed
minimum requirements
consequently bolstering patient
care and safety



STAY CURRENT

with advances in laboratory
medicine, technology, regulations



PURSUE

laboratory excellence with
industry best practices

Accreditation to Elevate Quality and Mitigate Risk

CAP Laboratory Accreditation Program



Discipline-specific Checklists



Collaborative Peer Inspections



Educational Resources

A Blueprint for Running a High-Quality Laboratory



CAP Accreditation Checklists

- Simplify compliance
- Provide best-in-class standards
- Guided by expertise from all laboratory participants
- Incorporate best practices
- Written in straightforward language
- Updated annually
- Suitable for all staff

Discipline-Specific Checklists



For guidance across the laboratory *and* at the bench level

Director Assessment

Laboratory General

All Common

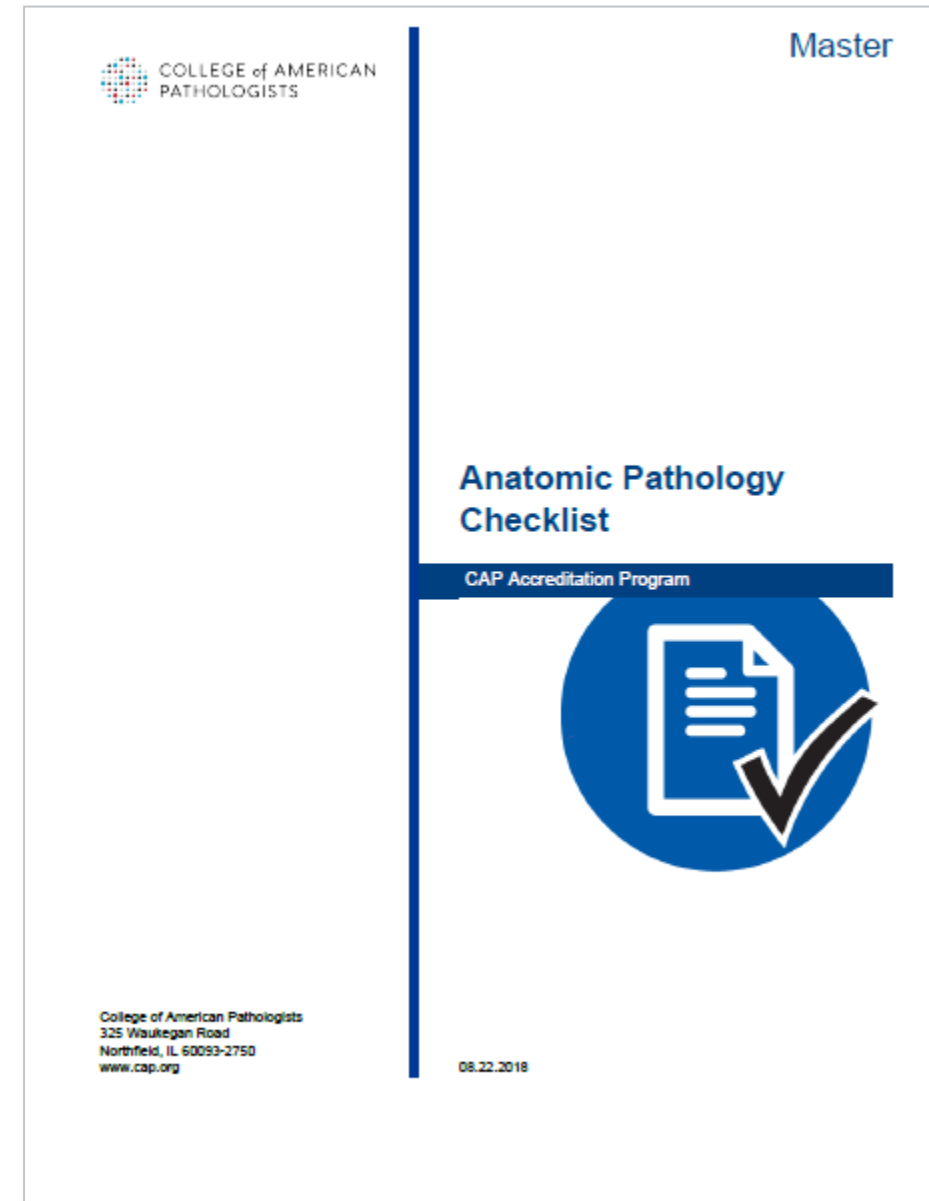
Hematology & Coagulation	Anatomic Pathology	Clinical Biochemical Genetics
Chemistry & Toxicology	Cytopathology	Point of Care
Urinalysis	Cytogenetics	Biorepository
Microbiology	Forensic Drug Testing	Flow Cytometry
Transfusion Medicine	Histocompatibility	Limited Service Lab
Immunology	Molecular Pathology	Reproductive Lab (Embryology & Andrology)

Customized Checklists Based on Testing Menu



NO SURPRISES

Customized checklists ensure
you know what will be
inspected before the
inspection based on your
exact testing menu



Incorporating ISO Concepts to Strengthen Quality



Laboratory General Checklist

Expanding & Enhancing Quality Management Requirements

Requirement	Description	Resource
GEN.203010	Investigation of non-conforming events	Root Cause Analysis–Focus on Compliance webinar & toolbox*
GEN.20318	Corrective and preventative action	
GEN.20316	QM indicators of quality	Test utilization modules for CAP members
GEN.13806	Quality Management System	QMS–Focus on Compliance webinar*, QMS examples*, and QMED course (QMS Implementation Roadmap*)
GEN.20326	Assess QMS for effectiveness	

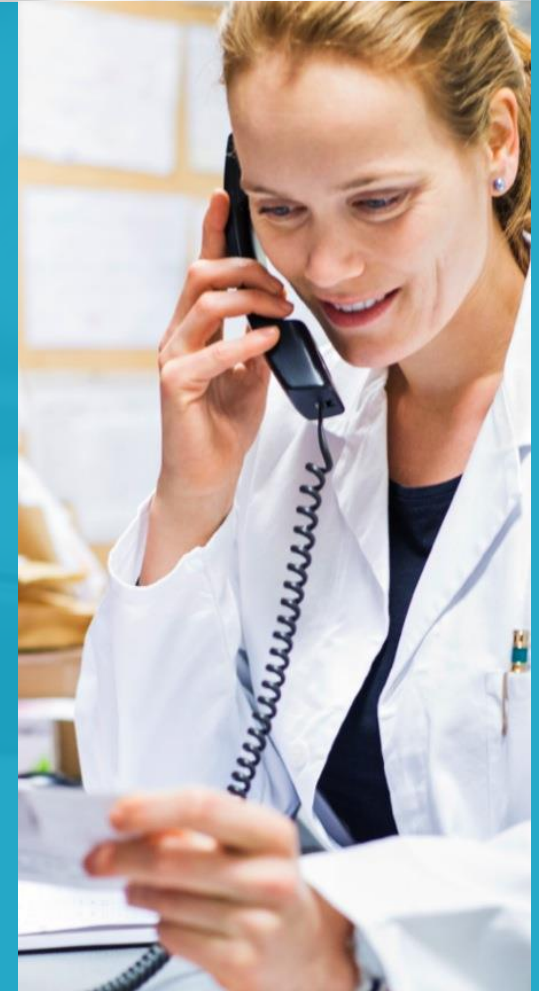
**Resources available in e-LAB Solution Suite*

Clarification and Compliance Guidance



Experienced Technical Specialist (Medical Technologist) available via phone (800-323-4040) or email (accred@cap.org)

- Clarify checklist requirements
- Provide guidance on compliance
- Educate on best practice



Peer Inspections Reduce Risk



Team inspections cover **all aspects of the laboratory** reducing risk

Teams match to **size, scope, expertise, and specialty** with laboratory services

Pathologist-led teams bring **real world experiences**

A collegial environment facilitates **peer-to-peer exchange** for mentoring opportunities

Peer inspections reduce risk by encompassing the entire laboratory



Other accreditors use a “tracer” methodology, narrowing the focus of the inspection



A Unique Perspective Through Reciprocal Inspections



- **>10,000 laboratory professionals participate annually**
- **Gain fresh insights and share best practices**
- **Identify gaps in your own compliance**
- **Learn multiple ways to meet requirements**
- **~18 months after your anniversary date**

Thorough Inspection Team Training



Online Training

Coursework and tools for a successful inspection

Role specific training for Team Leader/Team Member

Earn CME/CE and SAM credit

Fast Focus on Compliance

Mini-vignettes providing supplemental training

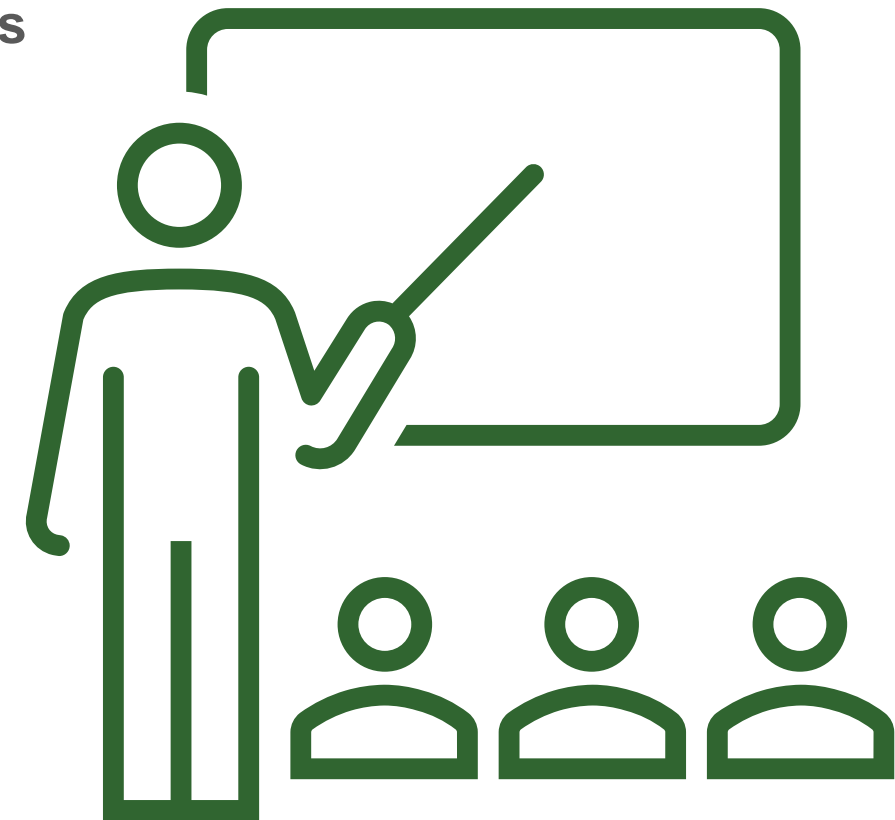
Practical approaches for handling new and perplexing topics

Real-world scenarios

Live Inspector Training

In-person events held annually

Opportunities to engage and interact with other trainees



What Program Participants Are Saying



“Being a CAP inspector has helped me become a better medical technologist and supervisor ... I know how to apply this knowledge to improve quality and enhance patient care.”

Kristin Neel, Technical Supervisor
TriCore Reference Laboratories

“CAP inspections provide a unique opportunity to speak with peers who are facing the same challenges you are.”

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

“When members of our staff serve on inspection teams, it can actually help us meet our own compliance requirements.”

Sheelagh Lindberg, MHA, BSMT(ASCP)
Administrative Director, Laboratory, Banner Baywood Medical Center,
Banner Heart Hospital/Laboratory Sciences of Arizona

Peer Inspection Options to Accommodate Your Needs



In-Person Inspection

- Designated inspection team visits facility on site
- Defined day and time for routine inspection
- Inspection typically completed in one day

Virtual Inspection

- Provides safety for both inspectors and the laboratory
- Uses technology to facilitate peer exchange like digital file transfer and live video stream
- Results in an accreditation decision

Advance Document Review

- Available for both in-person and virtual inspections
- Share select documents before the inspection with the inspection team

To learn more visit <https://www.cap.org/laboratory-improvement/accreditation/inspector-tools-and-training>

Affiliated Inspection Options



Coordinated Inspection

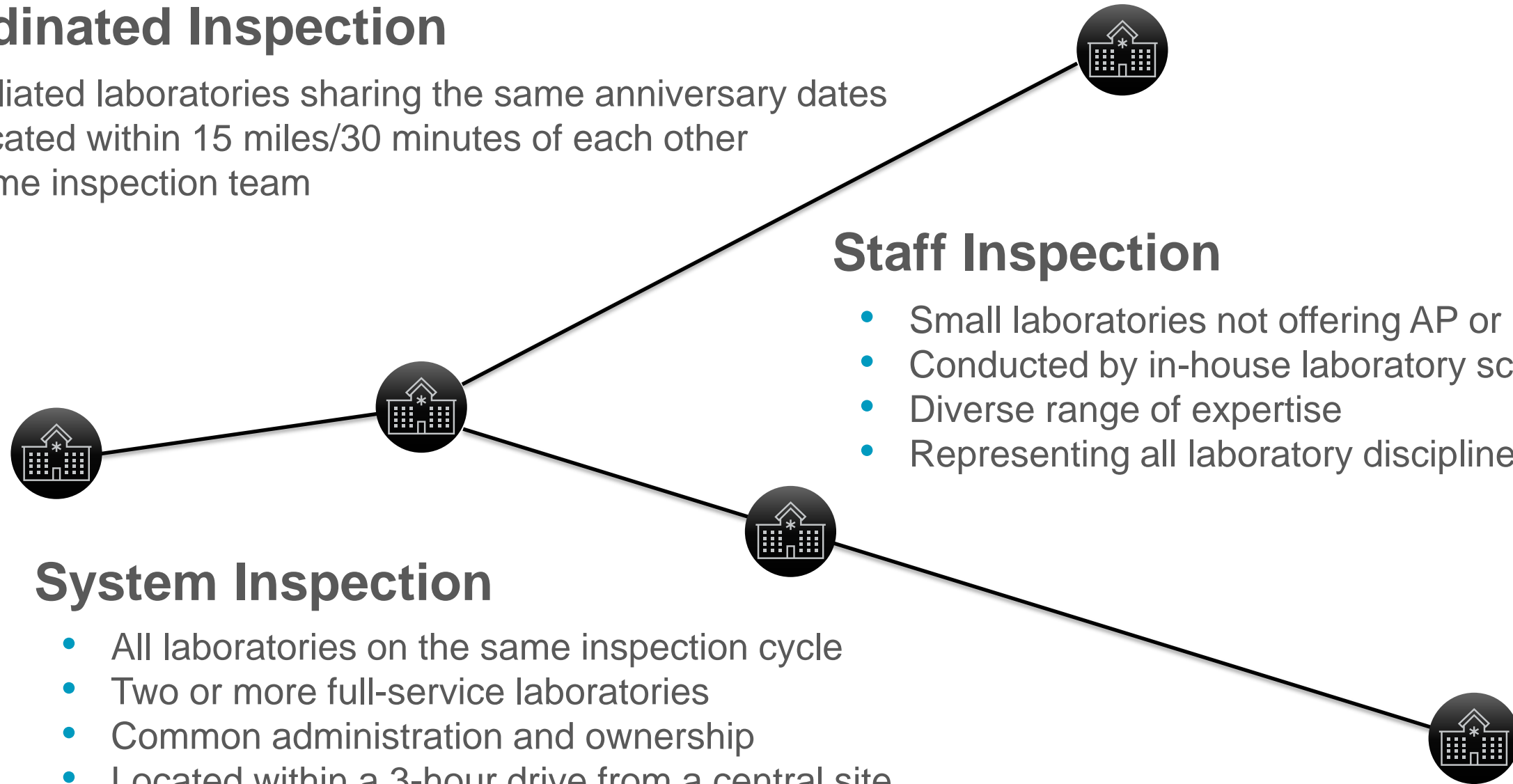
- Affiliated laboratories sharing the same anniversary dates
- Located within 15 miles/30 minutes of each other
- Same inspection team

Staff Inspection

- Small laboratories not offering AP or cytopathology
- Conducted by in-house laboratory scientists
- Diverse range of expertise
- Representing all laboratory disciplines

System Inspection

- All laboratories on the same inspection cycle
- Two or more full-service laboratories
- Common administration and ownership
- Located within a 3-hour drive from a central site
- Meet eligibility



A Journey Toward Standardization

An Integrated Network of Clinical Laboratories at St. Elizabeth Healthcare

Evolve and
elevate quality



Multiple sites of
varying size



Mitigate risk



Grow and adapt
over time

Complementary Education for Continuous Compliance



Focus on Compliance webinars

- Topics to navigate the ever-changing rules of compliance
- Get expert knowledge on best practices
- Suitable for laboratory directors, managers, and technologists

Fast Focus on Compliance vignettes

- Specialized content to supplement inspector training
- Practical approaches to handle new and perplexing topics
- Real-world scenarios for a clear understanding of requirements

e-LAB Solutions Suite online portal

- Obtain FAQ for >75 common deficiencies
- Access customized compliance checklists
- Download templates such as Competency, Analytical Validation & Verification
- Use toolboxes like IQCP, PT/EQA, Root Cause Analysis, Self & Post Inspection

Application/Reapplication Process

Accreditation Manuals/ Retention Guidelines

Laboratory Webinars

Focus on Compliance

Laboratory Inspection Preparation Course

Proficiency Testing (PT)/External Quality Assurance (EQA) Toolbox

PT Compliance Notice (PTCN)

Checklist Resources

Accreditation Checklists

Checklist Requirement Q&A

Templates

Quality Management

IQCP Toolbox

External Resources

CAP Laboratory Director Education, Information & Resources

Inspector Training & Tools

Mitigate Risk Using Real-Time Performance Data



Performance Analytics Dashboard
web-based reporting



- **Accreditation**
 - Manage your risk and compliance
 - Prepare for accreditation inspections
- **Proficiency testing**
 - Perform data analysis to mitigate risk by patterns & trends
 - Access evaluations, result forms, and participant summary reports
 - Benchmark your laboratory against your peers and CAP-wide performance
- **Reporting**
 - Focus on relevant details with in-depth analysis

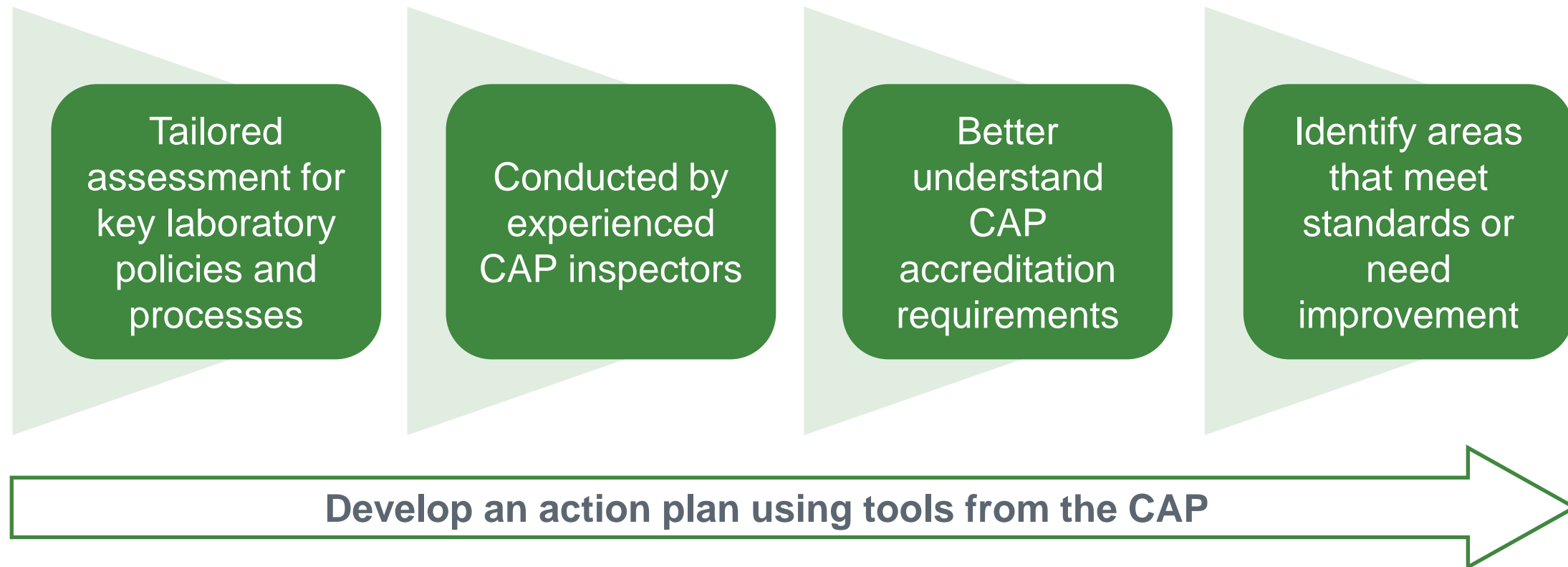
CAP Laboratory Accreditation Programs

Optional Assessment to Help You Attain Accreditation

Know Where You Stand Before You Start

CAP Accreditation Readiness-Assessment (CARA)

Gain reassurance by preparing with an on-site evaluation



Specialty Accreditation Programs

Program	Description
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.
Forensic Drug Testing Accreditation Program	Designed for the unique needs of forensic drug testing laboratories and intent for laboratories that perform confirmatory testing.
Biorepository Accreditation Program	Designed for biorepositories that collect, process, store, and distribute biospecimens for research.
CAP 15189 Accreditation Program	Accreditation to the ISO 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 efficiencies. Accreditation from the CAP's Laboratory Accreditation program is a prerequisite.

Begin Your Path to Laboratory Excellence!

Let Us Help Start Your Journey Today

Email Us

accred@cap.org

Get Started

cap.org/laboratory-improvement/accreditation

Learn More

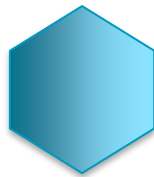
cap.org



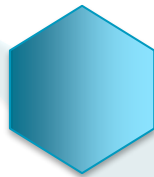
Become CAP Accredited

CAP Laboratory Accreditation Program

Experience
Operational Excellence
held at the highest standard
of quality to ensure the best
patient care



Discipline-specific Checklists



Collaborative Peer Inspections



Educational Resources

Interactive Session

**We invite you to engage with our speakers
by submitting a question**

Questions?

Learn more about laboratory accreditation

<https://www.cap.org/laboratory-improvement/accreditation>