Cleveland Clinic

Accreditation in the Clinical Arena

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Section of Molecular Pathology

Clinical Laboratory Improvement Amendments of 1988 (CLIA)

- **Primary legislation governing laboratory regulation in the U.S.**
  - administered by CMS
  - covers approximately 244,000 laboratory entities.
- **Application to all testing for "diagnosis, prevention, or treatment of any disease … or the assessment of the health of, human beings."**
  - CLIA certification required for participation in Medicare and Medicaid
- **Focus on analytical validity**
  - QA/QC components in quality systems framework
  - reflect flow of specimen from receipt and test results to reporting
  - track preanalytic, analytic, and postanalytic phases of testing
- **Regulations 121 pages in Code of Federal Regulations**
- **Tests are classified as waived, moderate complexity, high complexity**
  - progressively increased regulatory stringency
- **Emphasizes development of and compliance with written policies and procedures**

CLIA Requirements

- Standards
  - validation
  - quality systems
  - proficiency testing
  - record keeping
  - facilities administration
  - certification
  - personnel
  - inspections
  - user fees
  - enforcement
  - sanctions
- Processes for new test validation

- Continual monitoring and improvement of processes
  - patient confidentiality
  - specimen ID and integrity
  - complaints
  - evaluation of PT
  - competencies
  - review assessments and corrective actions
  - revise policies and procedures to prevent recurrences
  - discuss assessment activities with staff and document assessment activities

CLIA Certification

- Many laboratories obtain CLIA-certification through accreditation by organizations such as the College of American Pathologists (CAP) or Joint Commission.
    - deemed compliant with CLIA
    - receive Certificate of Accreditation
    - standards must meet or exceed CLIA
- Labs in exempt states can receive CLIA-certification through state licensure
    - New York and Washington
- Laboratories licensed in specialties or subspecialties in which tests fall

Advantages of Accreditation

- Assists in development of performance standards
  - aids with research
  - improves education
- Ease developing uniform training
- Improve professional culture
- Facilitate data gathering process for publication and advancement of scientific basis of field

CAP Overview

- Established in 1946
- Leading organization for board-certified pathologists
- More than 18,100 members and 600 employees
- Headquarters: Northfield, Illinois; Advocacy office in Washington, DC

Headquarters: Northfield, Illinois, a suburb of Chicago

CAP Accreditation Overview

- Offering laboratory accreditation since 1963
- Helps laboratories achieve the highest standards of excellence
- More than 7,600 CAP-accredited laboratories in 50 countries
- Estimated 22,000 laboratories in 100 countries enrolled in the CAP's proficiency testing (PT) programs

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CAP Accreditation

- Sets high standards for clinical, anatomic, and specialty laboratories that address quality, efficiency, and safety:
- Extends beyond CLIA regulatory requirements
  - focuses on improving quality
  - encourages quality culture
- CAP performs biennial inspections
- Uses trained peer inspectors
- Self inspections required
- Laboratories need to adhere to checklist requirements
- CLIA only requires formal PT for 83 analytes, but CAP includes many more
- CAP helps facilitate interlaboratory proficiency exchanges
- Explicitly requires clinical validity, which can be documented by literature
- CAP programs help labs attain excellence in testing
- Leads in developing requirements for molecular oncology, cytogenetics, and reproductive medicine

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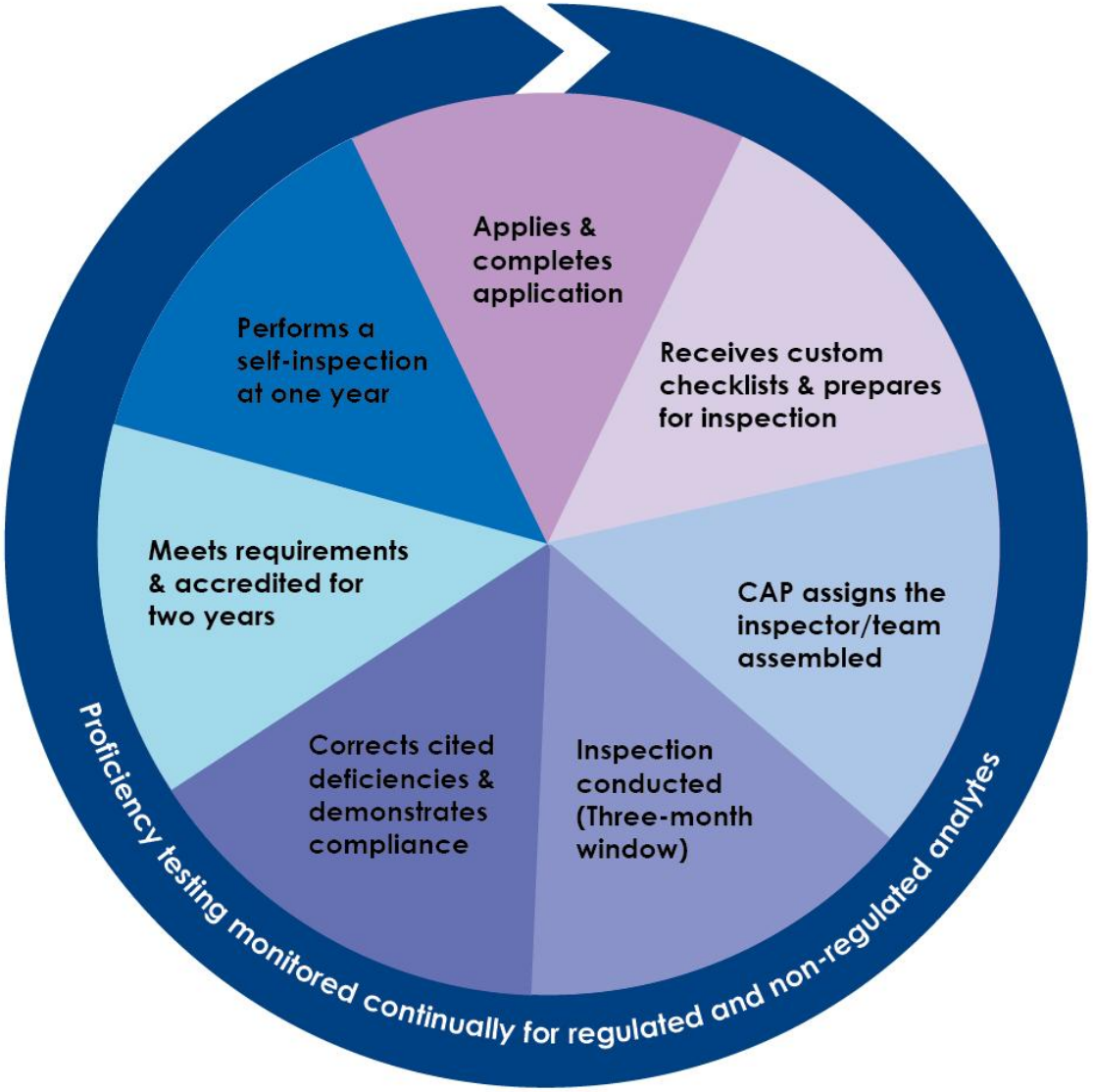
CAP Laboratory Accreditation Program: Two-Year Cycle



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CAP Standards for Laboratory Accreditation

Core principles of the CAP's Laboratory Accreditation Program

- Standard I – **Director and Personnel**
  - qualified, responsible for meeting standards, given authority
- Standard II – **Physical Resources**
  - nature, adequacy, safety, disabilities
- Standard III – **Quality Management**
  - extensive list of policies and procedures to ensure quality testing and patient safety
- Standard IV – **Administrative Requirements**
  - checklists, inspections, self assessment, records and documentation, terms of accreditation

Accreditation Checklists

- Laboratory General
- All Common
- Anatomic Pathology
- Team Leader Assessment of Director and Quality
- Chemistry and Toxicology
- Clinical Biochemical Genetics
- Cytogenetics
- Cytopathology
- Flow Cytometry
- Hematology and Coagulation
- Histocompatibility
- Immunology
- Limited Service Laboratory
- Microbiology
- Molecular Pathology
- Point-of-Care Testing
- Transfusion Medicine
- Urinalysis

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CAP Laboratory Accreditation Program: Value of Peer-Based Inspections

- Laboratory professional (pathologist, technologist, etc.)
  - Gains insight through interacting with peer professionals
  - First-hand knowledge to offer constructive feedback
- Promotes continuous education & improvement
- Inspectors with Specialty Expertise
- Working professionals exposed to new technologies
- Domestic and international inspections
- Staff Inspectors
  - Ancillary sites and large groups of limited service labs
  - Participate in all for-cause inspections

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TROUBLE

THE MURDER THAT NEVER WAS

People weekly

Wrongly imprisoned for her baby's death, a Missouri mother is finally freed

A "I will never forget," says Patricia Stallings of the day her son Ryan was taken fatally ill and the family's ordeal began.

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Every life deserves world class care.