

Beaumont

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Coord

Area: Laboratory-Quality

Key Words: GEN.26791

Applicability: All Beaumont Hospitals

Terms of Accreditation: College of American Pathologists (CAP)

Document Type: Guideline

I. PURPOSE AND OBJECTIVE:

- A. The purpose of this document is to define requirements which must be met in order to maintain accreditation with the College of American Pathologists (CAP) -Terms of Accreditation.
- B. The College of American Pathologists (CAP) plays a major role in the laboratory accreditation process. Generally, when a laboratory meets the CAP Laboratory Accreditation (LAP) Standards for Accreditation, the CAP will grant accreditation for a period of two years, *providing requirements are met*.

II. TERMS OF ACCREDITATION:

Accreditation by the CAP Accreditation Program is contingent on the compliance with the terms and obligations listed below:

- A. Cooperate in any CAP investigation or inspection and notify the CAP if the laboratory becomes:
 - 1. The subject of an investigation by a government entity (e.g. local, state or federal agency)
 - 2. The subject of a validation inspection
 - 3. The subject of adverse media-attention
- B. Notify the Commissioner if the laboratory discovers any actions by laboratory personnel that violate national, federal, state or local regulations.
- C. Have a written procedure for employees to communicate concerns about quality and safety to management and for management to investigate employee complaints. Refer to [Procedure for Laboratory Employees to Communicate Concerns Regarding Test Quality and Laboratory Safety](#).
- D. Incorporate corrective or preventive actions into the laboratory Quality Management Plan.
- E. Provide a trained inspection team comparable in size and scope to that required for your site inspection, if requested by the regional and/or state commissioner at least once during the two year accreditation period.
- F. Participate annually in a CAP accepted proficiency testing program.
- G. Notify the CAP and the Centers for Medicare and Medicaid Services (CMS), in writing 30 days prior to any

changes in the following: directorship, location, ownership, name, insolvency or bankruptcy.

- H. Notify the CAP when there is a change in test menu prior to beginning that testing or the laboratory permanently or temporarily discontinues some or all testing.
- I. Authorize the CAP to release its inspection and proficiency testing data and other information, required by law, to the appropriate regulatory/oversight agencies such as CMS, Department of Veterans Affairs, Department of Defense, Joint Commission or state agencies.
- J. Make available on a reasonable basis the laboratory's annual PT results upon request of any person.
- K. Allow CMS (or its agent) to perform a validation or compliant inspection at any time during the lab's hours of operation and permit CMS to monitor the correction of any deficiencies found through such an inspection
- L. Obtain a Clinical Laboratory Improvement Amendments (CLIA) certificate of Accreditation and pay all applicable fees as a CLIA-certified laboratory.
- M. Submit a completed *Self-Evaluation Verification Form* in the interim (*i.e. self-inspection*) year.
- N. Adherence to the Terms of Use for the CAP Certification Mark of Accreditation:
 - 1. Must not change the mark or combine it with any other graphics
 - 2. Must provide samples of all uses if requested
 - 3. Must comply with guidelines that CAP might publish for its use in the future
 - 4. Must stop using the mark immediately if accreditation is withdrawn
 - 5. Must stop using the mark within 30 days if CAP discontinues its use
- O. Submit only documentation and other materials to the CAP that have been de-identified of all protected health information (PHI) in accordance with the requirements of the Health Insurance Portability and Accountability Act (HIPAA) and its implementing regulations, unless the laboratory must submit PHI to the CAP in order to respond to a deficiency or patient complaint.
- P. Refrain from copying or distributing the CAP checklists or any content thereof except for the use by inspectors in conducting a CAP inspection and by the laboratory in preparing for such an inspection.
- Q. It is appropriate for both Clinical and Anatomic Pathology staff to be involved with the accreditation process:
 - 1. Are aware of (and understand) the CAP *terms of accreditation* and,
 - 2. Remain compliant with these defined requirements.

III. ANNIVERSARY DATES:

The CAP inspection anniversary dates are as follows:

- A. Farmington Hills and Livonia Laboratory: January 23
- B. Grosse Pointe and Lenox Laboratories: May 25
- C. Royal Oak Laboratory: January 30
- D. Troy Laboratory: April 2
- E. Dearborn Laboratory: October 22
- F. Taylor, Trenton, Wayne and Canton Laboratories: December 7

IV. REFERENCES:

- A. Letter of Accreditation, College of American Pathologists. *Current document.*
- B. Laboratory General (Inspection) Checklist, College of American Pathologists. *Current document.*

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
CLIA Site Licensed Medical Directors	Ann Marie Blenc: System Med Dir, Hematopath	8/27/2024
CLIA Site Licensed Medical Directors	Subhashree Mallika Krishnan: Staff Physician	8/26/2024
CLIA Site Licensed Medical Directors	Ryan Johnson: OUWB Clinical Faculty	8/15/2024
CLIA Site Licensed Medical Directors	Muhammad Arshad: Chief, Pathology	8/15/2024
CLIA Site Licensed Medical Directors	Kurt Bernacki: System Med Dir, Surgical Path	8/15/2024
CLIA Site Licensed Medical Directors	Jeremy Powers: Chief, Pathology	8/15/2024
CLIA Site Licensed Medical Directors	Masood Siddiqui: Staff Pathologist	8/14/2024
CLIA Site Licensed Medical Directors	Hassan Kanaan: OUWB Clinical Faculty	8/14/2024
CLIA Site Licensed Medical Directors	John Pui: Chief, Pathology	8/14/2024
Policy and Forms Steering Committee Approval (if needed)	Michele Sedlak: Lab Quality Coord	8/14/2024
	Sarah Britton: VP, Laboratory Svcs	8/14/2024
Operations Directors	Brittnie Berger: Dir Sr, Lab Operations	8/14/2024
Operations Directors	Christopher Ferguson: Dir, Lab Services	7/17/2024
Operations Directors	Joan Wehby: Dir, Lab Services	7/16/2024
Operations Directors	Amy Knaus: Dir, Pathology Service Line	7/11/2024
Operations Directors	Elzbieta Wysteppek: Dir, Lab Operations B	7/11/2024
	Michele Sedlak: Lab Quality Coord	7/11/2024

Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne