


Name of Policy: Laboratory Compliance with College of American Pathologists (CAP) Terms of Accreditation			
Policy Number: 3364-107-317		Effective date: 01/04/2025	
Approving Officer: Medical Director, Clinical Pathology		Original effective date: 01/12/2009	
Responsible Agent: Director, Clinical Pathology Administrative Director, Lab			
Scope: Pathology Laboratory University of Toledo Medical Center			
Key words: College of American Pathologists (CAP), accreditation terms, federal investigation, adverse media attention, test menu.			
<input type="checkbox"/>	New policy proposal	<input type="checkbox"/>	Minor/technical revision of existing policy
<input type="checkbox"/>	Major revision of existing policy	<input checked="" type="checkbox"/>	Reaffirmation of existing policy

(A) Policy statement

Laboratory must comply with all College of American Pathologists (CAP) terms of accreditation in order to maintain two-year accreditation on a continuous basis.

(B) Purpose of policy

To help ensure UTMC laboratory maintains the high standard for which it received CAP accreditation.

(C) Procedure

1. Notification of the CAP for the following:

- a. Investigation of the laboratory by a government entity or other oversight agency, or adverse media attention related to laboratory performance; notification must occur no later than two working days after the laboratory learns of an investigation or adverse media attention. For laboratories subject to US regulations, this notification must include any complaint investigations conducted or warning letters issued by any oversight agency, e.g. Centers for Medicare and Medicaid Services (CMS), State Department of Health, The Joint Commission, Federal Drug Administration (FDA), and Occupational Safety and Health Administration (OSHA).
- b. Laboratory validation inspection.

- c. Discovery of actions by laboratory personnel that violate national, federal, state, or local laws and regulations.
 - d. Change in laboratory test menu prior to beginning that testing or the laboratory permanently or temporarily discontinues some or all testing.
 - e. Change in laboratory directorship, location, ownership, name, insolvency, or bankruptcy; notification must occur no later than 30 days prior to the change(s); or, in the case of unexpected changes, no later than two working days afterwards. Laboratories subject to US regulations must also notify CMS.
2. Provision of a trained inspection team comparable in size and scope if requested by CAP at least once every two-year accreditation period.
3. Cooperation with the CAP and the CMS when the laboratory is subject to a CAP or CMS complaint investigation or validation inspection.
4. Adherence to the Terms of Use for the CAP Certification Mark of Accreditation.
5. For laboratories subject to US regulations, availability, on a reasonable basis of the laboratory's annual proficiency testing results upon request of any person.

<p>Approved by:</p> <p><u>/s/</u> Name: Amira Gohara, M.D. Title: Medical Director, Clinical Pathology</p> <p><u>1/10/2025</u> Date</p> <p><i>Review/Revision Completed by:</i></p> <p><i>Joshua Otiso, Administrative Director, Lab</i></p>	<p>Policies Superseded by This Policy:</p> <ul style="list-style-type: none">• <p>Initial effective date: 01/12/2009</p> <p>Review/Revision Date: 01/04/2025</p> <p>Next review date: 01/04/2027</p>
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