


Name of Policy: <u>Blood Gas Laboratory Compliance with CAP Terms of Accreditation</u>		 Effective date: 2/3/2025 Original effective date: 9/2017	
Policy Number: 3364-136-CBGL-11			
Approving Officer: Medical Director, Blood Bank Program			
Responsible Agent: Director, Respiratory Care Services			
Scope: The University of Toledo Medical Center Respiratory Care Services Department			
Key words: Blood Gas, Inspection, Accreditation, Patient, Testing			
<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

The Blood Gas Laboratory must comply with all College of American Pathologists (CAP) terms of accreditation to maintain a 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

The following requirements must be met to maintain continuous two-year accreditation:

1. Participate in an inspection team of a size and composition similar to that required for your inspection and perform at least one inspection during the two-year accreditation cycle, if asked to do so by Commissioner.
2. Submit an application for re-inspection in sufficient time that the re-inspection may be accomplished prior to your anniversary date.
3. Successfully participate in the CAP surveys or a CAP-approved alternative proficiency testing program.
4. Notify the commission of changes in location, ownership, directorship, location, insolvency, or bankruptcy of the laboratory. Notification must occur prior to the change(s); or, in the case of unexpected changes, no later than two working days afterwards.
5. Notify the Commission when there is a change in the test menu. Notification must occur prior to starting new patient testing.
6. Cooperation with CAP when the laboratory is subject to a CAP investigation or inspection.

7. Submit a completed Self-Evaluation Verification Form in the interim year.
8. Have a written procedure for employees to communicate concerns about quality and safety to management to investigate employee complaints. Incorporate corrective or preventive actions into the laboratory Quality Management plan.
9. Authorize the CAP to release its inspection and proficiency testing data to the appropriate regulatory oversight agencies such as CMS, The Joint Commission, UNOS, or state/provincial agencies.
10. Submit only documentation and other materials to 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 of 1996 and its implementing regulations, see 45 C.F.R. 164.514(b) unless the laboratory must submit PHI to CAP to respond to a deficiency or patient complaint.
11. Refrain from copying or distributing the CAP Check lists or any content thereof except for use by inspectors in conduction of a CAP inspection and by the laboratory in preparing for such an inspection.
12. Adherence to the Terms of Use for the CAP Certification Mark of accreditation.
13. CAP must be notified if any of the following occurs:
 - a. Investigation of the laboratory by a government entity or other oversight agency, or adverse media attention related to laboratory learns of an investigation or adverse media attention. This is to include any complaint investigations conducted or warning letters issued by any oversight agency (i.e., CMS, State Department of Health, The Joint Commission, FDA, OSHA).
 - b. CAP must be notified as soon as laboratory finds itself to be subject to validation inspection.
 - c. Discovery of actions by laboratory personnel that violate national state or local regulations.

<p>Approved by:</p> <p>/s/</p> <hr/> <p>Melissa Kukiela BSRC, RRT Director, Respiratory Care Services</p> <p>2/3/2025</p> <hr/> <p>Date</p> <p>/s/</p> <hr/> <p>Lauren Stanoszek, MD Medical Director</p> <p>2/3/2025</p> <hr/> <p>Date</p> <p><i>Review/Revision Completed by:</i> Director, Respiratory Care Services</p>	<p>Policies Superseded by This Policy:</p> <ul style="list-style-type: none">• <i>n/a</i> <p>Initial effective date: 09/2017</p> <p>Review/Revision Date:</p> <p>09/11/2017 02/22/2019 03/15/2021 03/23/2023 02/03/2025</p> <p>Next review date: 02/3/2027</p>
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