


<b>Name of Policy:</b> <b>Point of Care (POC) Glucose Testing on Critically Ill Patients</b>		 <b>Effective date:</b> 01/04/2025 <b>Original effective date:</b> 03/01/2015	
<b>Policy Number:</b> 3364-107-125			
<b>Approving Officer:</b> Medical Director, Clinical Pathology			
<b>Responsible Agent:</b> Director, Clinical Pathology Administrative Director, Lab			
<b>Scope:</b> Pathology Laboratory University of Toledo Medical Center			
Key words: POC testing, glucose, critically ill definition, Roche glucometers, Federal Drug Administration (FDA) limitation clause			
<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

Point of Care (POC) Glucose Testing on critically ill patients must be performed following compliance standards required by CMS, CLIA and CAP. Glucose testing on critically ill patients using the Roche Inform II Blood Glucose meters is not permitted.

(B) Purpose of policy

To assure that all Glucose testing performed at the point of care conforms to federal and other regulatory requirements.

Recently the FDA has enacted labeling changes specific to the use of waived whole blood glucose devices. The limitation clause “The performance of this system has not been evaluated on the critically ill” has been added. Use of glucose meter testing outside of its FDA approved intended use is not permitted. Each facility must define “critically ill” for their institution for the POC glucose testing.

(C) Procedure

For the specific use of Glucose meters, critically ill at the University of Toledo Medical Center will be defined as “a patient on mechanical ventilation with a mean arterial pressure less than 60 mmHg despite the use of pressors”. Glucose testing on these patients must be performed on a venous or arterial blood sample sent to the Pathology laboratory.

<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><b>Policies Superseded by This Policy:</b></p> <ul style="list-style-type: none"><li>•</li></ul> <p>Initial effective date: 03/01/2015</p> <p>Review/Revision Date: 01/04/2025</p> <p>Next review date: 01/04/2027</p>
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