

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0975982	(X3) Date Survey Completed 05/03/2023
Name of Provider or Supplier Middle Georgia Chest & Medical Center, Llc	Street Address, City, State 1209 N Columbia Dr, Milledgeville, GA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on May 3, 2023. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on the standard operating procedure (SOP) and staff interview, the laboratory director failed to approve, sign, and date the procedure and changes for the procedure manual before use. The Finding include: 1. SOP revealed the laboratory director failed to approve, sign, and date the procedure and changes for the procedure manual before use. The procedure manual was last signed in 2019. 2. During an interview with Testing Personnel #1 (CMS-209) on May 3, 2023 at approximately 11:20 AM, confirmed the laboratory director failed to approve sign, and date the procedure manual.</p>
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to</p>

identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on review of the Proficiency Testing (PT) records and staff interview, the Testing Personnel (TP) and Laboratory Director (LD) failed to ensure PT results were reviewed and the attestation document was signed. Findings include: 1. Review of PT records hematology for 2021-3rd event, revealed the Testing Personnel (TP) and Laboratory Director (LD) did not sign the attestation. 2. During an interview with the Testing Personnel #1(CMS 209) on May 3, 2023 at approximately 12:15 PM, in the breakroom, confirmed that the PT results were not reviewed and the attestation statement document was not signed by the Testing Personnel (TP) or the Laboratory Director (LD).