

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0710614	(X3) Date Survey Completed 05/23/2025
Name of Provider or Supplier Miller County Hospital	Street Address, City, State 209 North Cuthbert Street, Colquitt, 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 recertification survey was performed on May 22, 2025. The facility was found to be NOT in compliance with all applicable CLIA requirements for specialties /subspecialties for 42 CFR.
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Blood Bank(BB) Quality Control (QC) Log, the BB bank Log, and staff interview, the Laboratory performed Reagent QC on expired Red Cell (RC) reagents on 02/13/2024. Findings: 1. Review of the BB QC log for 02/13/2024, the BB RC reagents it was confirmed that the Ortho A2 cells and the B cells expired on 02 /12/2024. There was BB testing performed on 02/13/2025, as follows: Two units of blood were retyped for type verification One patient was retyped for type confirmation and two units were crossmatched on this patient 12 units were retyped for confirmation of group and type One patient had a group and type performed 2. Interview with the Laboratory Manager, on May 22, 2025, at approximately 4pm, in the Dialysis Room, confirmed the above statement</p>
D6007	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1)</p> <p>(e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;</p>

This STANDARD is not met as evidenced by:
 Based on review of the Blood Bank(BB) Quality Control (QC) Log, BB bank Log, and staff interview, the Laboratory Director (LD) failed to ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance for the analytic phase of the BB Reagent QC. Findings: 1. Review of the BB QC log for 02/13/2024, the BB RC reagents it was documented that the Ortho A2 cells and the B cells expired on 02/12 /2024. There was BB testing performed on 02/13/2025, as follows: Two units of blood were retyped for type verification One patient was retyped for type comfermation and two units were crossmatched on this patient 12 units were retyped for confirmation of group and type One patient had a group and type performed 2. Interview with the Laboratory Manager, on May 22, 2025 at approximately 4pm in the Dialysis room, confirmed that the Laboratory Director failed to provide quality laboratory services for all aspects of test performance for the analytic phase of the BB Reagent QC.

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES
 CFR(s): 493.1413(b)(8)(iii)

(b)(8)(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;

This STANDARD is not met as evidenced by:
 Based on review of the Blood Bank(BB) Quality Control (QC) Log and the BB bank Log, and staff interview, the Laboratory Technical Consultant (TC) failed to note that the Reagent QC was performed on expired Red Cell (RC)reagents on 02/13/2024. Findings: 1. Review of the BB QC log for 02/13/2024, the BB RC reagents it was documented that the Ortho A2 cells and the B cells expired on 02/12/2024. There was BB testing performed on 02/13/2025, as follows: Two units of blood were retyped for type verification One patient was retyped for type comfermation and two units were crossmatched on this patient 12 units were retyped for confirmation of group and type One patient had a group and type performed 2. Interview with the Laboratory Manager on May 22, 2025 in the Dialysis Room, confirmed that the Laboratory Technical Consultant (TC) failed to note that the Reagent QC was performed on expired Red Cell (RC)reagents on 02/13/2024.