Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0710614	05/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Miller County Hospital	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 25, 2023. The facility was found to be NOT in compliance with the CLIA conditions and standards for specialties /subspecialties for 42 CFR. D5200: (Condition) General Laboratory Systems 493.1230 NOTE: The CMS-2567 (Statement of Deficiencies) is an official , legal document,. All information must remain unchanged except for entering the Plan Of Correction (POC), correction dates, and the signature space. Any discrepancy n the original deficiency citation(s) will be reported the the Georgia Regional Office (RO) for referral the Office of the Inspector General (OIG) for possible fraud if the information is inadvertently changed by the provide/supplier, the State Survey Agency (SA) should be notified immediately.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) documents and staff interview, the Laboratory Director failed to monitor and evaluate the overall quality of the general laboratory systems, and verify the performance of twice a year verification to demonstrate the analyte Ammonia was performing as required for the year 2021, and 2022. Reference D5217
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)

	At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on the review of American Proficiency Institute (API) Proficiency Testing (PT) documents and confirmed by staff interview, the laboratory failed to at least twice annually verify the accuracy of the analyte Ammonia for the years 2021, 2022. and 2023 Findings: 1. Review of the API PT documents for 2021 the laboratory received a score of 0% for the 1st and 2nd event for the analyte Ammonia. The laboratory was unsuccessful for both events. For 2022 the laboratory received a score of 100% for the 1st event and 0% for the 2nd event for the analyte Ammonia. The laboratory was unsuccessful for 1out of 2 events. For 2023 the laboratory received a score of 100% for the 1st event and 100% for the off scheduled event for the analyte Ammonia. The laboratory was successful for event #1 and the off schedule event for 2023. 2. Staff interview with the General Supervisor on May 25, 2023 at approximately 3pm in the Dialysis Center, confirmed the above aforementioned statements.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on the review of American Proficiency Institute (API) Proficiency Testing (PT) documents and confirmed by staff interview, the Laboratory Director (LD) failed to ensure the laboratory at least twice annually verified the accuracy of the analyte Ammonia for the years 2021, 2022, and 2023, Findings: 1. Review of the API PT documents for 2021 the laboratory received a score of 0% for the 1st and 2nd event for the analyte Ammonia. The laboratory was unsuccessful for both events. The LD and the GS reviewed the API PT results For 2022 the laboratory received a score of 100% for the 1st event and 0% for the 2nd event for the analyte Ammonia. The laboratory was unsuccessful for 1 out of 2 events. The LD and the GS reviewed the API PT results For 2023 the laboratory received a score of 100% for the 1st event and 100% for the off scheduled event for the analyte Ammonia. The laboratory was successful for event #1 and the off schedule event for 2023.The LD and GS reviewed the API PT results 2. Staff interview, with the General Supervisor , on May 25, 2023, at approximately 3:30 pm, in the Dialysis Center, confirmed the above aforementioned statements. The LD and the GS reviewed the API PT reults