

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0652220	(X3) Date Survey Completed 02/06/2024
Name of Provider or Supplier Ray County Memorial Hospital	Street Address, City, State 904 Wollard Blvd, Richmond, MO	
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
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedures, Siemens Dimension EXL 200 chemistry analyzer quality control (QC) from December 1, 2023 to December 31, 2023, patient results, and interview with technical supervisor (TS) #1, the laboratory failed to include two acceptable control materials of different concentrations for Albumin (ALB) for 2 of 31 patient testing days. Findings: 1. Review of laboratory procedure "Quality Control Policy" states "Occurs when two consecutive control values fall outside the same 2SD. The run is rejected." 2. Review of the Siemens Dimension EXL 200 chemistry analyzer QC from December 1, 2023 to December 31, 2023 showed two acceptable levels of ALB QC was not performed on December 13 and 14, 2023. 3. Review of the patient results showed the laboratory reported 6 ALB patients on December 13, 2023 and 12 ALB patients on December 14, 2023 while QC was not acceptable. 4. Interview with the TS #1 on February 6, 2024 at 10:00 AM confirmed the laboratory failed to include two control materials each day of patient testing for ALB.</p>
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must</p>

have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

Based on observation of laboratory analyzers, lack of instrument comparisons, and interview with the technical supervisor (TS) #1, the laboratory failed to have a system that twice a year evaluates and defines the relationship between test results using different instruments in 2022, 2023 and to date February 6, 2024. Findings: 1.

Observation of the laboratory analyzers showed an iSTAT analyzer in the laboratory and a second iSTAT analyzer in the respiratory department, both analyzers perform sodium, potassium, chloride, calcium, glucose, blood urea nitrogen (BUN), carbon dioxide (CO₂), creatinine, pH, partial pressure of oxygen (PO₂) and partial pressure of carbon dioxide (PCO₂). 2. Lack of instrument comparisons showed the laboratory had no documentation to evaluate and define the relationship between the two iSTAT analyzers twice a year in 2022, 2023 and to date February 6, 2024. 3. Interview with the TS #1 on February 6, 2024 at 11:00 AM, confirmed the laboratory failed to have a system that twice a year evaluates and defines the relationship between test results using different instruments.