

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0046175	(X3) Date Survey Completed 06/14/2022
Name of Provider or Supplier Bates County Memorial Hospital	Street Address, City, State 615 W Nursery St, Butler, 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
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on the observation of laboratory pipettes, the lack of function check documentation and interview with the technical supervisor (TS) #2, the laboratory failed to perform and document function checks to verify the accuracy of eight of eight laboratory pipettes for 2020, 2021 and to date June 14, 2022. Findings: 1. Observation of laboratory pipettes showed the last function check for the Eppendorf 10-100 pipette, MLA- 50, MLA-75, MLA-100, MLA-200, MLA-500, MLA-1000 pipettes and a Thermo Finnpipette 100-1000 pipette was performed in September 2019. 2. The laboratory could not provide documentation showing that the pipettes were evaluated in 2020, 2021, or to date June 14, 2022. 3. Interview with the TS #2 on June 14, 2022 at 1:00 PM confirmed the laboratory failed to perform and document function checks to verify the accuracy of laboratory pipettes in use for patient testing.</p>
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--</p>

Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of iStat blood gas EG7+ quality control (QC) records, and interview with the technical supervisor (TS) #2, the laboratory failed to verify the QC criteria in LIS matched QC package insert for control material providing quantitative results. Findings: 1. Interview with TS #2 stated the laboratory used QC package insert ranges for the iStat blood gases. 2. Review of the iStat TriControls Level 1 Lot # 391145 package insert showed: Na: 121-129 mmol/L iCa: .77-.93 mmol/L PCO₂: 55-77 mmHg PO₂: 69-99 mmHg HCT: 20-26 QC values for Level 1 in laboratory LIS: Na: 121-130 mmol/L iCa: .76-.92 mmol/L PCO₂: 54.3-69.3 mmHg PO₂: 70-100 mmHg HCT: 19-25 3. Review of the iStat TriControls Level 3 Lot # 321141 package insert showed: PCO₂: 16.1-28.7 mmHg PO₂: 124-168 mmHg QC values for Level 3 in laboratory LIS: PCO₂: 16-28.6 mmHg PO₂: 126-170 mmHg 4. Interview with TS #2 on June 14, 2022 at 1:30 PM confirmed the laboratory failed to verify QC criteria in LIS matched QC package insert for acceptability of control materials providing quantitative results.