

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0705741	(X3) Date Survey Completed 01/10/2025
Name of Provider or Supplier Nell J Redfield Memorial Hospital	Street Address, City, State 150 N 200 W, Malad City, ID	
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
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>(b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on a review of calibration records, instrument documents for the Beckman Coulter AU480 and i-STAT 1 and an interview with the laboratory manager on 1/10 /2025, the laboratory failed to verify the reportable range at least once every six months for chemistry and blood gas analytes in 2023 and 2024. The findings include: 1. A review of calibration records and a lack of linearities for the Beckman Coulter AU480 identified that the laboratory failed to verify the reportable range for Albumin, Alkaline Phosphatase, ALT, AST, Amylase, Bicarbonate, Bilirubin Direct, Bilirubin Total, Calcium, Chloride, Cholesterol, Creatinine, Glucose, Phosphorus, Potassium, Iron, Lactate, Lipase, Magnesium, Sodium, Total Protein, Triglycerides, Urea</p>

Nitrogen (BUN) and Uric Acid at least every six months in 2023 and 2024. 2. A review of instrument documents and a lack of linearities for the i-STAT 1 identified that the laboratory failed to verify the reportable range for the blood gas analytes: pH, PO₂, PCO₂, TCO₂, HCO₃ and SO₂ at least every six months in 2023 and 2024. 3. An interview with the laboratory manager on 1/10/2025 at 8:08 am confirmed that the laboratory had not verified the reportable range of chemistry and blood gas analytes at least once every six months in 2023 and 2024. 4. The laboratory reports performing 173,801 chemistry tests and 193 blood gas tests annually.

D5545

HEMATOLOGY
CFR(s): 493.1269(b)(d)

(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed.

This STANDARD is not met as evidenced by:
Based on a random record review of Quality Control (QC) documentation and an interview with the laboratory manager on 1/9/2025, the laboratory failed to successfully perform two levels of QC every eight hours of patient coagulation testing. The findings include: 1. A random record review of QC documents from the ACL Top 300 for 2023 and 2024 identified that the laboratory failed to perform two levels of QC every eight hours for prothrombin time (PT) and partial thromboplastin time (PTT) testing. On 5/9/2023 level one QC was not performed and three (3) patient PT results and one (1) patient PTT result were reported. On 7/12/2024 level one QC was not performed and two (2) patient PT results were reported. 2. An interview with the laboratory manager on 1/9/2025 at 11:24 am confirmed the above finding. 3. The laboratory reports performing 1,041 PT and PTT tests annually.