

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  13D0705741	<b>(X3) Date Survey Completed</b>  01/25/2023
<b>Name of Provider or Supplier</b>  Nell J Redfield Memorial Hospital	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5429</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on a review of Beckman Coulter AU480 maintenance logs and an interview with the laboratory manager on 1/25/2023, the laboratory failed to perform maintenance as required by the manufacturer. The findings include: 1. A random review of Beckman Coulter AU480 maintenance logs identified that the laboratory failed to perform monthly maintenance which included cleaning the sample probe and reagent probe wash wells, cleaning the mix bar wash wells, cleaning the wash nozzle unit and checking the tube mounting joints and cleaning the DI water tank, DI filter, and sample probe filter in December 2021, April 2022 and November 2022. 2. A random review of Beckman Coulter AU480 maintenance logs identified that the laboratory failed to perform quarterly Ion-Selective Electrode (ISE) maintenance which included replacing the roller tubes for MID solution dispense and mixture aspiration and replacing the pinch valve tubing in November 2022. 3. A random review of Beckman Coulter AU480 maintenance logs identified that the laboratory failed to perform every other week ISE maintenance which included manually washing the mix bars, liquid level sensors, sample pot and sample pot tubes in December 2021, April 2022, September 2022, October 2022 and November 2022. 4. A random review of Beckman Coulter AU480 maintenance logs identified that the laboratory failed to perform weekly ISE maintenance which included enhanced cleaning of the electrode line for three of four weeks in December 2021, four of four weeks in September 2022 and two of four weeks in October 2022. 5. An interview</p>

with the laboratory manager on 1/25/2023 at 10:39 am confirmed that the laboratory failed to document the above maintenance. 6. The laboratory reports performing 91,845 tests annually on the Beckman Coulter AU480.

**D5445**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(1)(2)(g)

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--  
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a random record review of chemistry and hematology quality control (QC) documentation and an interview with the laboratory manager on 1/25/2023, the laboratory failed to include two levels of QC each day of patient testing. The findings include: 1. A random record review of chemistry QC performed on the Beckman Coulter AU480 identified that the laboratory failed to document two levels of QC on 6/8/2021 for high-density lipoprotein (13 patients reported), on 12/2/2021 for total protein (9 patients reported), on 4/22/22 for calcium (17 patients reported) and on 9/12/22 for alkaline phosphatase (25 patients reported). 2. A random record review of hematology QC performed on the Beckman Coulter DXH identified that the laboratory failed to document two levels of QC on 7/26/2021 for complete blood count (17 patients reported) and on 4/27/2021 and 4/28/2021 for red blood cells (43 patients reported). 3. An interview with laboratory manager on 1/25/2023 at 1:54 pm confirmed the above findings. 4. The laboratory reports performing 98,284 chemistry tests and 38,936 hematology tests annually.