Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0445429	08/15/2023
Name of Provider or Supplier	**Street Address, City, State**	
Nevada Regional Medical Center	800 S Ash, Nevada, 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
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--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 Siemens Dimension EXL with LM chemistry quality control (QC) records, and interview with the general supervisor (GS) #1, the laboratory failed to establish criteria for acceptability of control materials providing quantitative results. Findings: 1. Review of the Siemens Dimension EXL with LM QC records showed the laboratory did not establish, document, and define statistical parameter criteria (mean and standard deviations) for acceptability of quantitative chemistry QC. 2. Review of Siemens Dimension EXL with LM analyzer showed alkaline phosphatase level 1 QC range of 93-133 U/L. The laboratory could not provide documentation for establishment of the QC range. 3. Review of Siemens Dimension EXL with LM analyzer showed alkaline phosphatase level 2 QC range of 400-440 U/L. The laboratory could not provide documentation for establishment of the QC range. 4. Review of Siemens Dimension EXL with LM analyzer showed total bilirubin level 1 QC range of 1.06-1.34 mg/dl. The laboratory could not provide documentation for

	establishment of the QC range. 5. Review of Siemens Dimension EXL with LM analyzer showed total bilirubin level 2 QC range of 4.61-5.21 mg/dl. The laboratory could not provide documentation for establishment of the QC range. 6. Interview with the GS #1 on August 15, 2023 at 1:00 PM confirmed the laboratory failed to establish criteria for acceptability of control materials providing quantitative results.