Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0445429	08/31/2021
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
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's "Quality Control Action Plan", June, July, and August 2021 quality control records and interview with the technical supervisor (TS) #1, the laboratory failed to follow quality control (QC) procedure before reporting patient's test results. Findings: 1. Review of the laboratory's "Quality Control Action Plan", states " 2-2S violation (2 consecutive controls exceed the mean by 2 SD.) is an unacceptable quality control result." 2. Review August quality control results for total bilirubin showed the 2 standard deviation (SD) range in Cerner database for total bilirubin Liquichek 1 lot # 56950 QC was 0.99-1.27. On 08/02/2021 the quality control value was 1.30 and on 08/03/2021 was 1.30. Three patients test results had been reported on 08/03/2021 after an unacceptable quality control result on 08/03 /2021 with no remedial QC actions taken. 3. Interview with TS #1 on August 31, 2021 at 11:00 AM confirmed the laboratory did not follow procedure and run acceptable quality control prior to reporting patient test results.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: Based on lack of documentation of 2020 and 2021 Gem Premier 3000 blood gas quality control (QC) logs and interview with the Technical Supervisor (TS) #1, the laboratory failed to test one sample of control material each 8 hours of patient testing. Findings: 1. Review of Gem Premier 3000 blood gas QC showed no documentation of blood gas QC every 8 hours of patient testing. Review of QC from January 1, 2020 to date August 31, 2021 showed 442 patient test results were reported when QC was not documented. 2. Interview with the TS #1 on August 31, 2021 at 10:30 AM confirmed the laboratory failed to document one sample of blood gas control material each 8 hours of patient testing.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on the lack of documentation of blood gas quality control (QC), lack of monthly review of blood gas statistical reports and interview with the technical supervisor (TS) #1, the laboratory director failed to ensure the quality control (QC) programs are established and maintained to assure the quality of laboratory services and to identify failures in quality as they occur in 2019/2020 and to date August 31, 2021. Findings: 1. Review of the laboratory's "Quality Control Action Plan "stated that "will be collated monthly and statistical reports will be generated. Statistical report variance such as standard deviations (SD) and coefficient of variance (CV), and /or other data comparison will be reviewed." 2. Lack of documentation of monthly review for 2019/2020 and to date August 31, 2021 blood gas QC showed no review by the laboratory director to assure the quality of the testing and to identify failures in quality. 3. Interview with the TS #1 on August 31, 2021 at 11:00 AM confirmed, the laboratory director failed to ensure the QC programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.