Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0445429	05/01/2025
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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on review of BioRad quality control (QC), lack of quality control package inserts, and interview with the general supervisor (GS) #1, the laboratory failed to retain QC package inserts from January 2022 to April 2024. Findings: 1. Review of chemistry QC showed the laboratory used BioRad assayed chemistry QC for the analytes: ammonia, ethanol, acetaminophen, B-hcg, carbamazepine, digoxin, ferritin, free T4, gentamycin, tpsa, phenytoin, salicylates, thyroid stimulating hormone, valproic acid, vancomycin, lithium, theophylline, phenobartibol, vitamin B12, folate, tobramycin, troponin HS, myoglobin, CKMB, nt-pro-bnp, urine microalbumin, urine protein, urine sodium, urine creatinine, hemoglobin A1C, vitamin D, direct bilirubin, total bilirubin, rcrp, spinal fluid glucose, spinal fluid total protein, and procalcitonin. 2. Lack of quality control package inserts showed the laboratory failed to retain QC package inserts from January 2022 to April 2024. 3. Interview with the GS #1 on April 22, 2025 at 1:30 PM, confirmed the laboratory failed to retain chemistry QC package inserts for the last 2 years.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that

	provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observations and record review the laboratory failed to meet the condition of analytic systems for hematology, chemistry, histology, and microbiology. The laboratory failed to follow the written procedure for gram stains (Refer to D5401); the laboratory failed to provide a procedure for replacing stains used for frozen sections (Refer to D5403); the laboratory failed to verify the correct lot number and expiration date was entered into the coagulation analyzer for the ISI value in use (Refer to D5411); the laboratory failed to include two controls materials of different concentrations each day of patient testing on the Dimension EXL-200 (Refer to D5447); the laboratory failed to document how criteria was established for acceptability of control materials providing quantitative results for 26 analytes (Refer to D5469); the laboratory failed to document the quality of the staining materials on day of use for frozen sections (Refer to D5473); and the laboratory failed to ensure all control materials for the Dimension EXL-200 were accurate before reporting patient test results (Refer to D5481).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, gram stain quality control (QC) records for April, May and June 2024, patient testing log, and interview the general supervisor (GS) #1, the laboratory failed to follow the written procedure for gram stains for 6 of 28 testing days in 2024. Findings: 1. Review of laboratory procedure "Gram Satin" states "The gram staining procedure is checked and recorded for each new batch of stains and daily when a gram stain is performed." 2. Review of gram stain QC records for April, May and June 2024 showed no gram stain QC documented on April 24, 2024, April 25, 2024, May 13, 2024, June 2, 2024, June 10, 2024, and June 24, 2025. 3. Review of patient testing logs showed the laboratory performed eight patient gram stains while QC was not performed. 4. Interview with the general supervisor (GS) #1 on April 22, 2025 at 1:00 PM confirmed the laboratory failed to follow the written procedure for gram stains.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of

	results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory procedures and interview with the general supervisor (GS) #1, the laboratory failed to provide a procedure for replacing stains used for frozen sections. Findings: 1. Review of laboratory procedures showed no procedure for replacing stains used for frozen sections. 2. Interview with the general supervisor #1 on April 22, 2025 at 1:00 PM confirmed the laboratory failed to provide a procedure for replacing stains used for frozen sections.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation of the Sysmex CA-600 coagulation analyzer, review of the Siemens Healthineer Dade Innovin package insert and interview with the general supervisor (GS) #1, the laboratory failed to verify the correct lot number and expiration date was entered into the coagulation analyzer for the International Sensitivity Index (ISI) value in use. Findings: 1. Observation of the Sysmex CA-600 coagulation analyzer showed innovin lot number 564643 with expiration date January 12, 2026 in use. 2. Review of the Siemens Healthineer Dade Innovin package insert showed lot number 564641 with expiration date December 15, 2025 in use. 3. Interview with the general supervisor #1 on April 22, 2025 at 1:00 PM confirmed the laboratory failed to verify the correct lot number and expiration date was entered into the coagulation analyzer for the ISI value in use.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by: Based on review of BioRad quality control (QC) package inserts, interviews,

	laboratory procedures, Dimension EXL 200 QC, and interview with the general supervisor (GS) #1, the laboratory failed to provide documentation of two control materials of different concentrations each day of patient testing for ammonia. Findings: 1. Review of chemistry QC showed the no package inserts for assayed chemistry QC for the analyte ammonia from January 2022 to April 2024. 2. Interview with the GS #2 stated a new lot number for ammonia was started on April 1, 2025. The old lot number was 54411 and 54412 the laboratory could not provide package insert. 3. Review of procedure states "1-2s This is the Warning Rule. If one control exceeds the mean +/- 2 sd, then the tech must consider other controls in the run (within) and in the previous runs before accepting the run and reporting results." 4. Review of the ammonia QC for March showed level 2 was unacceptable and not repeated on: March 21, 2025 March 22, 2025 March 27, 2025 March 28, 2025 5. Interview with the GS #1 on April 22, 2025 at 1:30 PM, confirmed the laboratory failed to provide documentation of two control materials of different concentrations each day of patient testing for ammonia.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(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. (d)(10)(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. (d)(10)(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. This STANDARD is not met as evidenced by: Based on review of the Siemens Dimension EXL chemistry analyzer quality control (QC) records, and interview with the general supervisor (GS) #1, the laboratory failed to document how criteria was established for acceptability of control materials providing quantitative results for 26 of 26 analytes. Findings: 1. Review of the Siemens Dimension EXL chemistry analyzer QC records showed the laboratory used unassayed QC. The laboratory could not show how they established, documented, and defined statistical parameter criteria (mean and standard deviations) for acceptability of quantitative QC for the analytes albumin, alkaline phosphatase, ALT, amylase, blood urea nitrogen, calcium, cholesterol, creatine kinase, carbon dioxide, creatinine, direct bilirubin, iron, glucose, lactic, lactate dehydrogenase, lipase, sodium, potassium, chloride, magnesium, phosphate, total protein, triglyceride, uric acid, AST, and total bilirubin. 2. Interview with the GS #1 on April 22, 2025 at 11:00 AM confirmed the laboratory failed to establish criteria for acceptability of control materials providing quantitative results.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.

	This STANDARD is not met as evidenced by: Based on review of laboratory procedures, patient reports, lack of stain quality records and interview with the general supervisor (GS) #1, the laboratory failed to document the quality of staining materials on day of use for frozen sections on November 26, 2024. Findings: 1. Review of laboratory procedure "Frozen Section" states "The pathologist judges the quality of the tissue section and stain each time a frozen section slide is produced." 2. Review of patient reports showed the laboratory performed a frozen section on November 26, 2024. 3. Lack of stain quality records showed the laboratory failed to document stain quality on November 26, 2024. 4. Interview with general supervisor #1 on April 22, 2025 at 1:00 PM confirmed the laboratory failed to document the quality of the staining materials on day of use for frozen sections.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers 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 chemistry BioRad Liquichek assayed quality control (QC) package insert, review of QC ranges in Dimension EXL-200 analyzer for 2 of 32 analytes, and interview with general supervisor (GS) #1, the laboratory failed to ensure the QC ranges in the Dimension EXL-200 analyzer were accurate before reporting patient test results. Findings: 1. Review of assayed chemistry Liquichek QC package insert revealed level 2 lot # 54442 ammonia acceptable range 163-253. 2. Review of Dimension EXL-200 chemistry analyzer revealed level 2 lot #54442 ammonia acceptable range 123-155. The laboratory could not provide documentation for how the range of 123-155 was established. 3. Interview with the GS #1 on April 22, 2025 at 12:15 PM confirmed the laboratory failed to ensure all control materials for the Dimension EXL-200 were accurate before reporting patient test results.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test report, review of Dimension chemistry analyzer print out, review of BioRad Liquichek package insert and interview with the general supervisor (GS) #1, the laboratory failed to ensure the patient test report units of measure was appropriate for the analyte ammonia. Findings: 1. Review of the patient test report showed the units of measure for the analyte ammonia as mcg/dl. 2. Review

	of the Dimension chemistry analyzer printout showed units of measure for the analyte ammonia as umol/L. 3. Review of the BioRad Liquichek quality control package insert showed units of measure for the analyte ammonia as ug/dl. 4. Interview with GS #1 on April 22, 2025 at 1:30 PM confirmed the laboratory failed to ensure the patient test report units of measure was appropriate for the analyte ammonia.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the general supervisor (GS) #1, the laboratory director failed to ensure appropriate staff evaluated ungraded PT results in 2024. Findings: 1. Review of 2024 Chemistry Core 1st event PT results revealed total bilirubin CH-02, CH-03 and CH-05 were not graded by the PT provider. The laboratory did not have documentation to show appropriate staff evaluated the ungraded samples. 2. Review of 2024 Chemistry Core 1st event PT results revealed sample Pilot CK-MB: PSC-01 and PSC-02 were not graded by the PT provider. The laboratory did not have documentation to show appropriate staff evaluated the ungraded samples. 3. Review of 2024 Chemistry Core 1st event PT results revealed sample Pilot D-dimer: PSC-01 and PSC-02 were not graded by the PT provider. The laboratory did not have documentation to show appropriate staff evaluated the ungraded samples. 4. Review of 2024 Chemistry Core 1st event PT results revealed sample Pilot NT pro-BNP: PSC-01 and PSC-02 were not graded by the PT provider. The laboratory did not have documentation to show appropriate staff evaluated the ungraded samples. 5. Review of 2024 Chemistry Core 1st event PT results revealed sample Pilot Trop I highsens: PSC-01 and PSC-02 were not graded by the PT provider. The laboratory did not have documentation to show appropriate staff evaluated the ungraded samples. 6. Interview with GS #1 on April 22, 2025 at 1:30 PM confirmed the laboratory director failed to ensure appropriate staff evaluated the ungraded results.