

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D0058654	(X3) Date Survey Completed 03/31/2026
Name of Provider or Supplier Northeastern Nevada Regional Hospital Lab	Street Address, City, State 2001 Errecart Blvd, Elko, NV	
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
D0000	A validation survey was conducted on March 31, 2026 , with the following standard level deficiencies cited.
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Lactic Acid Based on review of manufacturer's instructions, laboratories policy, patient test reports, and interview with general supervisor #1, the laboratory failed to follow the manufacturer's instructions (Siemens Atellica) and their own policy for specimen collection and handling with a 30-minute time frame prior to analysis for 3 of 71 lactic acids reviewed from January 1 to January 15, 2026 as evidenced by: 1. A review of the manufacturer's instructions for the lactic acids performed on the Siemens Atellica states, "Separate the plasma by centrifugation within 30 minutes. A delay in separation can lead to increase in lactate values." 2. A review of the laboratory's policy titled, "Lactate_3 (Lac_3)- Atellica CI 1900," states on pg. 2 "Separate the plasma by centrifugation within 30 minutes. A delay in separation can lead to increase in lactate values." 3. A review of the patient test reports for lactic acids from January 1 to January 12,2026 the following patients were over the 30-minute time frame: a. patient# 6561731 collection 1/6/2026 at 1200, received in laboratory on 1/6/2026 at 1237, 37 minutes total time. b. patient#6562106 collection 1/7/2026 at 1730, received in the laboratory on 1/7/2026 at 1819, 49 minutes total time. c. patient #6562270 collection 1/10/20206 at 1354, received in the laboratory on 1/10/2026 at 1508, 74</p>

minutes total time. 4. In interview with the general supervisor #1 at 0900 confirmed that three lactic acids did not make the laboratory's timeframes. 5. The laboratory performed 1,550 lactic acid tests in 2025.

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 lack of step-by-step procedure, review of the laboratory's textbook, and interview with general supervisor #1, the laboratory failed to have a step-by-step procedure on how to perform microscopic urines in 2025 through the date of the survey as evidenced by: 1. The laboratory could not provide a step-by-step procedure on how to perform a microscopic urinalysis. It did not include how much urine needed, how to set up the test, duration of centrifugation, and relative centrifugal force (RCF) 2. In review of the textbook Urinalysis and Body Fluids by Strasinger edition 2 pg. 89, that the lab presented as a reference, stated the following: "A standard amount of urine, usually between 10 and 15 ml, is centrifuged in a conical tube ... The speed of the centrifuge and the length of the time the specimen is centrifuged should be consistent. Centrifuge for 5 minutes at a relative centrifugal force (RCF) of 400 will produce an optimum amount of sediment with the least chance of damaging elements." 3. In interview with general supervisor #1 at 1330 confirmed that they did not have a step-by-step procedure which would include how many milliliters (mls) of urine needed to perform the test, duration of centrifugation, and RCF.

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 review of manufacturer's package insert, review of the laboratory's procedures, and interview with general supervisor #2, the laboratory failed to follow the Remel gram stain procedure since August 1, 2025, through the date of the survey, as evidenced by: 1. In review of the Remel package insert states the following: " Place the slide on a staining rack and overlay with gram crystal violet for 1 minute. Wash thorough with water and overlay with gram iodine mordant for 1 minute, flood with gram decolorizer until the solvent flows colorless the slide (10-30 seconds, rinse with water and overlay with gram safranin for 30 seconds." 2. In review of the laboratory's procedure titled, "Gram Stain" states the following: "Saturate the smear with crystal violet for 1 minute. Saturate the smear with iodine for 1 minute. Decolorize with gram decolorizer (acetone/alcohol) for 1-2 secs only ... Counterstain with safranin for 1 minute. 3. The laboratory's procedure does not match with the Remel manufacturer's instructions, effective date: 08/2025, in regard to decolorizer and safranin. 4. In

interview with general supervisor #2 at 1535 she stated that she does not use a timer and that she only takes 2 minutes for the entire procedure.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on direct observation, manufacturer's instructions, and interview with general supervisor #1, the laboratory failed to monitor room temperature where supplies were stored in the draw room for the last two years as evidenced by: 1. The manufacturer's instructions for the Becton Dickinson (BD) tubes (EDTA, Sodium Citrate, Serum Separator Tubes (SST) state, "store at 4-25 degrees C." 2. During a tour of the facility at 0852 the following supplies were stored in the draw room without temperature monitoring: 4- BD K2 EDTA lot#50515017 expiration date: 4-30-2026 27- BD Sodium Citrate lot#526010 expiration date: 6-30-2026 29- BD SST lot #530095 expiration date: 10-31-2026 3. The laboratory could not provide a temperature chart documenting the room temperature in the draw room. 4. In interview with general supervisor #1 at 0853, it was confirmed that the laboratory did not monitor room temperature per the manufacturer's instructions.