Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0522069	03/20/2024
Name of Provider or Supplier	**Street Address, City, State**	
North Idaho Urology	980 W Ironwood Dr #104, Coeur D'Alene, ID	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, the competency assessment policy, competency assessment records and an interview with the general supervisor (GS) on 3/20/2024, the laboratory failed to establish and follow written policies and procedures to assess competency of all laboratory personnel. The findings include: 1. A review of the CMS 209 identified two testing personnel, a general supervisor and laboratory director that also fulfilled the role of technical supervisor. 2. A review of the competency assessment policy identified that the laboratory failed to include instructions for performing a competency assessment of the GS. 3. A review of competency assessment records identified that the laboratory failed to have a competency assessment for the GS. 4. An interview with the GS on 3/20/2024 at 1:21 pm confirmed the above findings. 5. The laboratory reports performing 47,550 tests annually.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results.

	(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 a review of the laboratory's internal proficiency testing (PT) submission form, their PT policy and an interview with the general supervisor (GS) on 3/20/2024, identified that the laboratory failed to have complete instructions for verifying the accuracy of testing in the policy. The findings include: 1. A review of the PT submission forms for molecular microbiology identified that the three other laboratories under common directorship were to complete testing of sent blind samples, record results and send their results back to the GS at North Idaho Urology. 2. A review of the PT policy identified that the laboratory failed to include the complete process of splitting samples between the four laboratories. The policy failed to include the number of samples to be split, the acceptability criteria, the timeframe for testing and grading and a process to prevent communication between facilities before results were graded by the laboratory director. 3 An interview with the GS on 3 /20/24 at 1:49 pm confirmed that the laboratory failed to have a policy with step by step instruction for PT. 4. The laboratory performs 46,800 molecular microbiology tests annually.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a direct observation, lack of documentation and an interview with the general supervisor (GS) on 3/20/2024, the laboratory failed to calibrate pipettes used for molecular microbiology testing. The findings include: 1. During the laboratory tour on 3/20/2024 a direct observation of four eppendorf adjustable pipettes identified that the laboratory failed to calibrate since purchase in 2020. 2. A lack of laboratory documents identified that the laboratory failed to have documentation of pipette calibrations. 3. An interview with the GS on 3/20/2024 at 3:28 pm confirmed that the laboratory had not calibrated the four pipettes. 4. The laboratory reports performing 46,800 molecular microbiology tests annually.