Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0522069	07/25/2018
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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) review and an interview with the laboratory lead, the laboratory failed to test proficiency samples from American Association of Bioanalysts (AAB) in the same manner as it tests patient samples since the last survey on June 7, 2016. Findings: 1. A record review of the AAB urine culture, extent 3, PT program subscribed by the laboratory revealed the laboratory reported only gram negative or gram positive organisms and not presumptive genus identification of organisms as performed on patient samples. 2. An interview on July 25, 2018 at 12:30 PM, with the laboratory lead, confirmed the laboratory failed to properly report the proficiency testing urine culture tests in the same manner as the laboratory tests and reports patient samples.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods

	This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory lead, the laboratory failed to test the American Association of Bioanalysts (AAB) proficiency testing (PT) samples for urine cultures by the same personnel who perform patient testing since the last survey on June 7, 2016. Findings: 1. An AAB PT record review revealed the laboratory failed to rotate the urine culture PT samples with the second testing personnel who performed patient testing since the last survey. 2. An interview on July 25, 2018 at 11:30 AM, with the laboratory lead, confirmed the laboratory failed to rotate the proficiency samples from AAB among all personnel who perform patient tests since the last survey.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and an interview with the laboratory lead, the laboratory director failed to sign the attestation statements from the American Association of Bioanalysts (AAB) for the specialty of microbiology and chemistry from January 2017 through July 2018. Findings: 1. An AAB PT record review from 2017 through 2018, revealed the laboratory director failed to sign the attestation statements for the specialty of microbiology and chemistry. 2. An interview on July 25, 2018 at 12:10 PM, with the laboratory lead, confirmed the laboratory director failed to sign the attestation statements from 2017 and 2018 events.
D5002	BACTERIOLOGY CFR(s): 493.1201 If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on observation, records review, and interview, the condition of bacteriology is not met based on the findings in D5471, D5477, D5507, and D5787.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory lead, the laboratory failed to verify the accuracy of microscopic examinations of urine sediment, semen,

	and fungal presence at least twice annually since the last survey on June 7, 2016. Findings: 1. A record review of revealed the laboratory failed to document the accuracy at least twice annually for microscopic examinations of urine sediment, the presence and motility of post-vasectomy semen samples, and fungal elements from culture plates since the last survey. 2. An interview on July 25, 2018 at 1:45 PM, with the laboratory lead, confirmed the laboratory failed to document the accuracy of the three microscopic tests at least twice 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 procedure review and an interview with the laboratory lead, the laboratory procedure for urine cultures, fungal tests, and prostate specific antigen (PSA) failed to include all the requirements for specimen processing and handling, specimen acceptability, criteria for control and calibration procedures, limitations in test methodologies, and pertinent literature references since the last survey on June 7, 2016. Findings: 1. A record review of the procedure manual confirmed that the procedure for urine cultures and fungal presence failed to include step-by-step test performance for interpretation and presumptive identification of microorganisms. 2. A record review of the procedure manual confirmed that the procedure for PSA failed to include specimen, reagent, control, and calibration handling and the criteria for acceptability and limitations in testing. 3. An interview on July 25, 2018 at 2:35 PM, with the laboratory lead, confirmed the laboratory only uses the Tosho AiA-360 manual for the operating instructions for PSA testing and failed to ensure all procedure manual requirements are met.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper

	use. This STANDARD is not met as evidenced by: Based on observation and an interview with the laboratory lead, the laboratory staff failed to follow the manufacturer's requirement for storage of external control materials for prostate specific antigen (PSA) performed on the Tosoh AiA-360 analyzer. Findings: 1. An observation of the laboratory freezer on July 25, 2018 at 2: 35 PM revealed the BioRad Liquicheck Immunoassay Plus Control Levels 1, 2, and 3 for PSA tests was in use by the laboratory and not labeled with expiration dates. The manufacturer states to keep the controls in the refrigerator at 2-8 C for up to 14 days after thawing. 2. An interview on July 25, 2018 at 2:45 PM, with the laboratory lead, confirmed the laboratory refreezes the control material every day and then throws them away after 2 weeks.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory lead, the laboratory failed to check each new lot or shipment of indole and catalase for negative and positive reactivity from the dates reviewed in March 2018 and July 2018. Findings: 1. A quality control document review for the indole and catalase biochemical tests revealed the laboratory failed to perform a negative control on indole and catalase tests when performing weekly quality control. 2. An interview on August 2, 2018 at 11:15 AM, with the laboratory lead, confirmed the laboratory only performed a positive control on the biochemicals as part of the lab's weekly quality control procedure.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on an observation, a record review, and an interview with the laboratory lead, the laboratory failed to document each batch of media for sterility, its ability to

	support growth and/or select or inhibit specific organisms, or produce a biochemical response since the last survey on June 7, 2016. Findings: 1. An observation of the laboratory refrigerator on July 25, 2018 at 2:45 PM, revealed there was Bile Esculin agar, Eosin Methylene Blue (EMB) agar and TSA w/ 5% Sheep blood agar. 2. A record review revealed the laboratory failed to perform quality control procedures before or concurrent with initial use for patient urine cultures nor have an Individualized Quality Control Plan for the microbiology media. 3. An interview on July 25, 2018 at 1:35 PM, with the laboratory lead, confirmed the laboratory does not perform quality control only the microbiology media, but retains the media labels and certificates from the manufacturer.
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a procedure review and an interview with the laboratory lead, the laboratory failed to check antimicrobial agents each day tests are performed with the appropriate organisms to ensure the procedure produces the correct response from the dates reviewed between February 2017 and July 2018. Findings: 1. A review of the urine cultures performed on proficiency testing and patient tests confirmed the laboratory failed to perform quality control each day tests are performed for the BD BBL Sensi-Discs. 2. An interview on July 25, 2018 at 1:35 PM with the laboratory lead, confirmed the laboratory performs quality control on the Sensi-Discs each week.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on a patient record review, laboratory culture worksheets, and an interview with the laboratory lead, the laboratory failed to maintain testing records including the media used for testing, colony description and quantitation, inhibition zone sizes, and the technician and date of performing the testing since the last survey on June 7, 2016. Findings: 1. A record review of the laboratory Urine Culture Worksheets revealed the laboratory worksheets failed to indicate: a. the type of media used. b. the colony description, quantitation, and morphology. c. the size of the zone of inhibition for

	each antibiotic. d. the person performing each step of testing from streaking of the plate to final sensitivity and the dates of test performances. 2. An interview on July 25, 2018 at 1:45 PM, with the laboratory lead, confirmed the laboratory does not record test performance activities on the laboratory worksheets.
D5805	TEST REPORT CFR(s): 493.1291(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 a patient report review and an interview with the laboratory lead, the laboratory test reports failed to indicate the date the test results were reported and the references ranges since the last survey on June 7, 2016. Findings: 1. Three patient report reviews in July 2018 revealed the laboratory reports failed to indicate the date the final test result was generated for PSA and urine culture tests. 2. The patient final reports for PSA tests also failed to indicate the normal ranges for the test procedure. 3. An interview on July 25, 2018 at 3:05 PM, with the laboratory lead, confirmed the laboratory workflow reports and the patient reports failed to state the normal ranges for the PSA tests and did not indicate the date the results were reported for tests performed in the laboratory.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and an interview with the laboratory lead, the laboratory director failed to provide overall management and direction for the laboratory. Refer to D6079, D6093, D6094, D6098, D6171, and D6120.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and

	493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on observation, record review, and an interview, the laboratory director failed to ensure the overall operation of the laboratory meets the CLIA regulations, to include the employment of qualified personnel to perform test procedures in microbiology and microscopic examinations since the last survey June 7, 2016. Findings: 1. Based on a personnel record review, the laboratory director failed to ensure 1 out 2 testing personnel listed on the CMS-209 was trained and competent in the performance of urine cultures and urine sediment examinations prior to testing patient samples for the past two years. 2. An interview on July 25, 2018 at 12:05 PM, with the laboratory lead, confirmed the practical nurse, who works as a backup testing personnel, failed to have documented training and competency assessments performed.
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 observation, record review, and an interview, the laboratory director failed to ensure the quality control program for microbiology meets the CLIA requirements since the last survey on June 7, 2016. Refer to D5477, D5507, and D5787.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment 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 record review and an interview, the laboratory director failed to ensure the quality assessment for the laboratory was established to identify errors and correct problems for the test systems in the laboratory. Findings: 1. Proficiency testing (PT) record reviews revealed the laboratory director failed to ensure the laboratory was performing biannual verification for microscopic examinations and testing PT samples as applicable to CLIA regulations. 2. Personnel record reviews revealed the laboratory director failed to ensure testing personnel are qualified, trained, and competent to perform all tests in the laboratory. 3. Procedure reviews revealed the laboratory procedures for urine cultures, fungal cultures, and prostate specific antigen tests failed to include all steps in the test performance. 4. Record review of quality control procedures for urine cultures failed to include all testing performed for the procedure and failed to meet the CLIA requirements for quality control testing in bacteriology.

D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a record review of personnel competency assessments and an interview with the laboratory lead, the technical consultant, who is the laboratory director, failed to evaluate the competency of 2 out of 2 testing personnel performing microscopic examinations for urine and post-vasectomy semen samples, prostate specific antigen (PSA), and urine cultures. Findings: 1. A review of personnel documents revealed the technical consultant failed to evaluate the competency for 1 out of 1 testing personnel performing urine microscopic and post-vasectomy semen exams, PSA, and urine cultures in 2017. 2. A review of personnel documents revealed the technical consultant failed to perform competency assessments on the second testing person acting as a backup that performs urine cultures since the last survey in 2016. 3. An interview on July 25, 2018 at 11:50 AM, with the laboratory lead, confirmed the technical consultant failed to assess and document the competency for both testing personnel for 2017, and never for the backup testing person.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on personnel records and the complexity of testing performed in the laboratory, the two testing personnel failed to qualify for high complexity testing in the specialty of bacteriology. Refer to D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)

	(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on personnel records and an interview with the laboratory lead, two testing personnel perform presumptive identifications and susceptibilities from urine cultures, but fail to qualify as high complexity testing personnel under 493.1489 since the last survey on June 7, 2016. Findings: 1. A record review of personnel education documents revealed the laboratory lead had a high school diploma and the second testing person failed to provide an educational diploma or transcript for qualification. 2. An interview on July 25, 2018 at 12:20 PM, with the laboratory lead, confirmed her educational background and that the second testing personnel was a licensed practical nurse.