Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0977077	07/15/2024
Name of Provider or Supplier	**Street Address, City, State**	
Idaho Urologic Institute	2855 E Magic View Dr, Meridian, 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
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 a review of proficiency testing (PT) documentation from the College of American Pathologists (CAP) and an interview with the technical supervisor (TS) on 7/15/2024, the laboratory failed to have testing personnel and the laboratory director attest to the integration of PT samples with routine testing of patient samples in 2023. The findings include: 1. A review of PT results from CAP identified that the laboratory failed to have the performing testing personnel and the laboratory director attest that PT samples were integrated with patient samples for hematology automatic differential 2023 event A and the laboratory director attest that PT samples were integrated with patient samples for hematology automatic differential 2023 event C. 2. An interview with the TS on 7/15/2024 at 9:49 am confirmed the above findings. 3. The laboratory reports performing 3,695 automated differentials annually.
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, competency assessment records and an interview with the technical supervisor (TS) on 7/15/2024, the laboratory failed to follow written policies and procedures to assess testing personnel in 2023 and 2024. The findings include: 1. A review of the CMS 209 form identified five (5) testing personnel, three (3) with start dates after the previous inspection on 8/9/2022. 2. A review of competency assessment records identified the laboratory failed to have annual competency for each system/test for two (2) testing personnel in 2023. 3. A review of competency assessment records identified the laboratory failed to have six month competency assessments for two (2) testing personnel in 2024. 4. A review of competency assessment records identified the laboratory failed to have documentation of initial training for one (1) testing personnel in 2024. 5. An interview with the TS on 7/15 /2024 at 8:53 am confirmed the above findings. 6. The laboratory reports performing 85,696 tests annually.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) documentation from the American Proficiency Institute (API), the College of American Pathologists (CAP) and an interview with the technical supervisor (TS) on 7/15/2024, the laboratory failed to document the review of PT results in 2023 and 2024. The findings include: 1. A review of PT documents from API for 2023 identified that the laboratory failed to document the review and evaluation of PT results for bacteriology events one (1) and three (3), hematology/coagulation events one (1), two (2) and three (3) and chemistry core events two (2) and three (3). 2. A review of PT documents from CAP for 2024 identified that the laboratory failed to document the review and evaluation of PT results for microbiology event one (1). 3. A review of PT documents from API for 2024 chemistry core event one (1) identified that the laboratory failed to evaluate unacceptable PT results for estradiol samples IA-01, IA-02, IA-03, IA-04 and alanine aminotransferase sample CH-01. 4. An interview with the TS on 7/15/2024 at 9:49 am confirmed the above findings. 5. The laboratory reports performing 85,696 tests annually.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) documents from the College of American Pathologists (CAP), the American Proficiency Institute (API) and an interview with the technical supervisor (TS) on 7/15/2024, the laboratory failed to review and evaluate PT scores that were given an artificial score of 100% in 2023 and

	2024. The findings include: 1. A review of PT documents from CAP for 2023 hematology automatic differential event A identified that the laboratory failed to evaluate results for red cell distribution width (RDW) samples F16 1-5 that were given an artificial score of 100% due to lack of a peer group. 2. A review of PT documents from CAP for 2023 hematology automatic differential event C identified that the laboratory failed to evaluate results for RDW samples F16 11-15 that were given an artificial score of 100% due to lack of a peer group. 3. A review of PT documents from CAP for 2023 semen analysis event A identified that the laboratory failed to evaluate results for anti-sperm antibody sample SEM-07 that was given an artificial score of 100% due to lack of consensus. 4. A review of PT documents from CAP for 2023 semen analysis event B identified that the laboratory failed to evaluate results for anti-sperm antibody sample SEM-18 that was given an artificial score of 100% due to lack of consensus. 5. A review of PT documents from CAP for 2024 semen analysis event A identified that the laboratory failed to evaluate results for anti-sperm antibody sample SEM-08 that was given an artificial score of 100% due to lack of consensus. 6. A review of PT documents from API for 2024 chemistry core event one identified that the laboratory failed to evaluate results for bilirubin samples CH-02, CH-03 and CH-05 that were given artificial scores of 100% due to result variance. 7. An interview with the TS on 7/15/2024 at 9:50 am confirmed the above findings. 8. The laboratory reports performing 85,696 tests annually.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of calibration records, instrument documents for the Alfa Wassermann Axcel and an interview with the technical supervisor (TS) on 7/15/2024, the laboratory failed to verify the reportable range with at least a minimum value, mid-point value and high value once every six months for chloride, sodium and potassium in 2023 and 2024. The findings include: 1. A review of calibration records and documents for the Alfa Wassermann Axcel identified that the laboratory failed to perform verifications of the reportable range for the analytes chloride, sodium and

	potassium at least every six months in 2023 and 2024. 2. An interview with the TS on 7/15/2024 at 11:31 am confirmed the above finding. 3. The laboratory reports performing 3,992 chloride, sodium and potassium tests annually.