Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0977077	08/24/2018
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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and an interview with the laboratory manager, the laboratory failed to document the evaluation of unsatisfactory PT results for the analyte sodium from the American Proficiency Institute (API) program 2017 event 1. Findings: 1. A review of PT results from API chemistry 2017 event 1, revealed the laboratory failed to document the evaluation and corrective action for the unsatisfactory sodium analyte. 2. An interview on August 24, 2018 at 9:15 AM, with the laboratory manager, confirmed the laboratory failed to document the evaluation and corrective action for the unsatisfactory analyte.
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 an observation, a record review, and an interview with the microbiology testing personnel, the laboratory failed to perform a positive and a negative control

	reaction for each substrate on the Microscan positive urine and negative urine panel identification system from the dates reviewed between July and August 2018. Findings: 1. An observation of the laboratory on August 24, 2018 at 9:30 AM, revealed a Microscan Autoscan 4 test system in use for gram-positive and gram-negative bacterial identification tests from urine specimens. 2. A quality control record review from Positive Combo 44 panels revealed the following biochemicals failed to include a positive and negative reaction: a. Panels were missing positive reactions: ARA. b. Panels were missing a negative reaction: OPT. 3. A quality control record review from Negative Urine Combo 73 panels revealed the following biochemicals failed to include a positive and negative reaction: a. Panels were missing positive reactions: CL4, TDA, and TO4. b. Panels were missing a negative reaction: NIT, OF/G, and P4. 4. An interview on August 24, 2018, at 10:15 AM, with the microbiology testing personnel, confirmed the control organisms failed to check each biochemical for a positive and negative reaction.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's 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 a record review and an interview with the microbiology testing personnel, the bacteriology laboratory failed to meet the Microscan identification system quality control acceptability requirements prior to reporting patient results in July and August 2018. Based on a record review and an interview with the microbiology testing personnel, the bacteriology laboratory failed to document quality control procedures performed on the MacConkey/Sheep Blood agar weekly since the last survey on October 7, 2016. Findings: 1. A quality control record review for the Positive Combo 44 panel ran on July 19, 2018 revealed the quality control strain 29213 S. aureus failed to meet the acceptability requirements before reporting 8 patient test results. 2. A quality control record review for the Negative Urine Combo 73 panel run on July 12, 2018 revealed the quality control strain 25922 E. coli failed to meet the acceptability requirements before reporting 13 patient test results. 3. A quality control record review for the Negative Urine Combo 73 panel run on July 26, 2018 revealed the quality control strain 27853 P. aeruginosa, 700603 K. pneumoniae, and 25922 E. coli failed to meet the acceptability requirements before reporting 23 patient test results. 4. A quality control record review for the Negative Urine Combo 73 panel run on August 16, 2018 revealed the quality control strain 49131 K. oxytoca failed to meet the acceptability requirements before reporting patient test results. 5. A quality control record review for the MacConkey/Sheep Blood agar revealed the laboratory failed to document the quality control results that were performed on a weekly basis. 6. An interview on August 24, 2018 at 10:45 AM with the microbiology principal, confirmed the quality control for the media failed to be documented and the Microscan Positive Combo 44 and the Negative Urine Combo 73 panels failed to meet acceptability requirements.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an

	ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory failed to establish and follow a Quality Assessment Plan (QAP) for the Microscan Autoscan 4 test system used for the identification of microbiology urine specimens and failed to develop a mechanism to monitor and correct problems in the microbiology laboratory since the last survey on October 7, 2016. Findings: 1. A review of the Individualized Quality Control Plan (IQCP) for tests performed on the Microscan revealed the laboratory failed to establish and follow a quality assessment plan. 2. A review of the procedure manual and record reviews revealed the laboratory failed to establish a system to monitor, assess, and correct problems in the microbiology laboratory. 3. An on August 24, 2018 at 11:00 AM with the microbiology testing personnel, confirmed the laboratory failed to write a QAP for the Microscan identification test system and failed to establish a quality assessment protocol for the laboratory.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory director failed to specify in writing the delegation of duties and responsibilities for the supervisor responsible for all phases of testing since the last survey on October 7, 2016. Findings: 1. A record review of policies and procedures revealed the laboratory director failed to specify in writing the delegation of duty for signing attestation statements for all proficiency testing (PT) performed in the laboratory. 2. An interview on August 24, 2018 at 9:30 AM with the laboratory manager, confirmed the laboratory director failed to delegate in writing the signing of attestation statements for the PT program.