Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D2016348	07/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Idaho Pain Clinic	1327 Superior St #101, Sandpoint, 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
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 proficiency testing (PT) record review and an interview with the laboratory director, the laboratory failed to verify the accuracy of urine Ethyl Glucuronide (EtG) performed on the Thermo Fisher Indiko Plus at least twice annually since April 20, 2017. Findings: 1. A PT record review revealed the laboratory failed to document the accuracy of EtG from urine specimens at least twice annually since 2017. 2. An interview on July 24, 2018 at 11:00 AM with the laboratory director, confirmed the laboratory failed to verify the accuracy of EtG.
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 record review and an interview with the laboratory director, the laboratory failed to perform and document calibration verification procedures at least once every 6 months on the Thermo Fisher Indiko Plus chemistry analyzer used to test drugs of abuse since April 20, 2017. Findings: 1. A record review of calibration reports for heroine, methadone metabolite and methadone, ecstasy, opiate, barbiturate, cocaine, cannabinoid, oxycodone, benzodiazepine, buprenorphine, and amphetamine revealed the laboratory failed to perform calibration verification on the analytes. 2. An interview on July 24, 2018, at 11:45 AM, with the laboratory supervisor, confirmed the laboratory failed to ensure that calibration verifications were perofrmed on all drugs of abuse analytes.
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 quality control records review and an interview with the laboratory director, the laboratory failed to meet the quality control requirements for Buprenorphine (Bup) performed on the Thermo Fisher Indiko Plus prior to reporting patient results for the dates reviewed between May 9 and May 23, 2018. Findings: 1. A review of quality control records from May 9, 2018 through May 23, 2018 revealed 31 patient Bup test results were reported when two out of two levels of controls were not within the manufacturer's acceptable range. 2. An interview on July 24, 2018 at 11: 15 AM, with the laboratory director confirmed the laboratory failed to verify the results of two levels of quality control materials were within the manufacturer's expected range prior to reporting patient Bup results.
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 patient report reviews and an interview with the laboratory director, the patient laboratory reports failed to include the test report date and specimen source for the 17 drug analytes performed since April 20, 2017. Findings: 1. A review of patient test reports revealed 2 out of 2 patient reports failed to include the test report date and the specimen source. 2. An interview on July 24, 2018 at 11:45 AM, with the laboratory director, confirmed the patient reports failed to include the test report date and specimen source since 2017.