Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2142104	12/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Innovative Laboratories	6911 Laurel Bowie Rd Suite 212b, Bowie, MD	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on laboratory procedure manual and record review and interview with the technical consultant (TC), the laboratory did not ensure that the procedure for running quality control (QC) on the toxicology analyzer accurately reflected the current practice in the laboratory. Findings: 1. The procedure, "General QC Policy," "Quality Control Guidelines" states that "General chemistry testing requires two levels every 24 hours." During an interview at 10:25 AM, the TC stated that QC is only run on the days that the laboratory tests patients; and 2. The procedure, "General QC Policy," "Routine QC Procedures," "Control Frequency" states that "It is also recommended to run controls post batch run when non-daily testing is the routine test interval; this will prevent the need for a run to run if the next batch day QC is out and the correction requires reagent, calibration, or analyzer corrective action(s)." The TC stated that the laboratory was not running QC post-batch because "it was not needed for toxicology testing"; and 3. The procedure, "Quality Assessment for Data Collection" states that "The following aspects will be monitored for laboratory compliance." Under the heading "Precision vs. Accuracy" it states "During review the total number of repeats will be calculated compared to total number of runs, this aspect will monitor analyzer and reagent performance, range acceptability, and stability." The TC stated that "the laboratory was not doing this and that it did not apply"; and 4. Part 2.d. of this same procedure states "Quality Control >4x in 10 days will be addressed. This aspect will be reviewed when addressed failed quality control runs, and it will assure that reagents are reliable, this rule will alert staff to take action prior to issues becoming

	severe enough to cause result inaccuracy or bias/trend possibilities." The TC stated that this was a "Westgard rule that doesn't apply to a tox lab." 5. During an interview on 12/13/19 at 12:30 PM, the TC confirmed that the written procedure manual did not accurately reflect the actual practice of the laboratory.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on procedure manual review and interview with the technical consultant (TC), the laboratory did not document the date of discontinuance for written procedures that were not performed. Findings: 1. During a tour of the laboratory at 11:30 AM, it was observed that the laboratory had a second procedure manual. 2. During an interview, the TC stated that the laboratory safety procedures were current, but that "the rest of it should be retired." The TC confirmed that the date of discontinuance of the procedures had not been documented and that the current safety procedures should be included in the primary procedure manual.
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 interview with the technical consultant (TC), the laboratory failed to label toxicology controls and reagents with the date they that were opened and their expiration date. Findings: 1. During a tour of the laboratory at 9:15 AM, it was observed that the "Bio-Rad Liquichek Opiate Controls (level 1, lot #43501, expiration date 10/31/20 and level 2, lot #43920, expiration date 5/31/21) and the "Bio-Rad Liquichek Urine Toxicology Controls (level S1E/low opiate, lot #71900, expiration date 8/31/20 and level S3, lot #67170, expiration date 12/31/20) were labeled with the opened date of 10/4/19 but not with the date of expiration; and 2. The "Cedia Buprenorphine" controls (level low, lot #73008237, expiration date 8/2019 and level high, lot #73008230, expiration date 8/2019) were labeled with the opened date of 10/4/19 but not with the date of expiration; and 3. The in-use "BC Wash Solution" on the AU480 chemistry analyzer (lot #M801044, expiration date 11/30/21) was not labeled with the date it was opened and put in to use. 4. During an interview on 12/13 /19 at 12:30 PM, the TC confirmed that the in-use toxicology controls and reagents were not labeled with the dates that they were opened and the expiration date.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other

	supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on quality control (QC) record review, observation, and interview with the technical consultant (TC), the laboratory failed to ensure that toxicology QC and calibrators were not used after they exceeded their expiration date. Findings: 1. The laboratory uses the Beckman Coulter AU480 chemistry analyzer to perform toxicology testing. During a tour of the laboratory at 9:15 AM, it was observed that the in-use "Bio-Rad Liquichek Opiate Controls (level 1, lot #43501, expiration date 10 /31/20 and level 2, lot #43920, expiration date 5/31/21) and the in-use "Bio-Rad Liquichek Urine Toxicology Controls (level S1E/low opiate, lot #71900, expiration date 8/31/20 and level S3, lot #67170, expiration date 12/31/20) were labeled with the opened date of 10/4/19. Review of the package insert showed that these controls expire after 30 days once opened. 2. QC Record review showed that these controls were run 2 times in November and 1 time in December, 2019; and 3. The in-use "Cedia Buprenorphine" controls (level low, lot #73008237 and level high, lot #73008230) both expired 8/2019. 4. QC Record review showed that controls were run 3 times in September, 2 times in October, 2 times in November, and 1 time in December, 2019. 5. During an interview on 12/13/19 at 12:30 PM, the TC confirmed that toxicology QC was run after the controls had expired.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on standard operating procedure manual (SOPM) and quality control (QC) record review and interview with the technical consultant (TC), the laboratory did not ensure that all corrective actions were documented when toxicology QC was unacceptable. Findings: 1. The procedure, "General QC Policy" states that "It is the responsibility of each laboratory worker to alert the Lab Director or his designee when quality control data indicates a problem. This is done using a QC REMEDIAL ACTION form or a CORRECTIVE ACTION form." 2. During an interview at 10:00 AM the TC stated that the laboratory did not have or use the above mentioned forms and that the testing person is supposed to write any QC problems on the "Quality Control Outlier Log." 3. The laboratory had one "Quality Control Outlier Log" which had 8 entries between 5/3/18 and 7/9/18. There were no other logs available at the time of the survey. 4. A review of QC records from 6/2018 to present showed that on 6 /14/18 and 6/22/18 both levels of buprenorphine QC were out of range; and 5. On 1/18 /19 the calibration was out; and 6. On 4/24/19 both levels of cocaine QC were out of range. 7. None of the above listed QC problems were documented on the "Quality

	Control Outlier Log." 8. During an interview on 12/13/19 at 12:30 PM, the TC confirmed that problems with toxicology QC and any corrective actions performed were not documented.
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 standard operating procedure manual (SOPM) and record review and interview with the technical consultant (TC), the laboratory failed to ensure that written quality assurance (QA) policies were followed to monitor, and correct problems identified in the analytic phase of patient testing. Findings: 1. The procedure, "Quality Assessment Review" states that "Specific aspects of laboratory testing will be monitored and reviewed for compliance by the Office Manager at least on a monthly basis" and that "All non-compliant findings will be assessed, and laboratory practices will be modified to assure policies are followed or revised according to work-flow needs by the Office Manager." The procedure also states that "The Quality Assessment/Assurance reports will be complied and evaluated by the Office Manager." 2. The procedure did not specify which aspects of the laboratory would be monitored or how the information would be used to effect quality improvement; and 3. Record review showed that there were no monthly QA reviews available at the time of the survey. 4. Procedure manual review showed that the procedure, "Job Summary," under the "Job Title: Technical Consultant" stated that the TC was "Responsible for: compile a quality assessment reports with dashboard tracking." During an interview on 12/13/19 at 11:00 AM, the TC stated that routine QA reviews are not provided to the LD, but "only if problems exist." The TC confirmed that the written QA policies were not followed to ensure that problems were identified and corrected in the analytic system.
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: Note: This is a repeat deficiency. The laboratory was cited during the initial survey on 8/15/2018 for not including the name of the laboratory where testing occurs on patient final reports. The plan of correction stated that this would be corrected. Based on review of patient final reports and interview with the technical consultant (TC), the

	laboratory did not have the correct name of the testing facility on the patient final report. Findings: 1. A random review of testing requisition forms and patient final reports from October, 2019 showed that for 2 of 2 patients the patient test request form had "Providence Pain Management Center" printed at the top; and 2. Final reports for these patients also had "Providence Pain Management Center" listed as the name of the laboratory where the testing was performed. 3. During an interview on 12 /13/19 at 12:30 PM, the TC stated that the name of the facility had changed to "Innovative Laboratories" in August, 2019 and confirmed that the name of the laboratory where testing is performed was not updated on the patient final reports.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on procedure manual review, review of the quality assurance (QA) plan, and interview with the technical consultant (TC), the laboratory director (LD) failed to ensure that quality control (QC) and QA procedures monitored overall operation of the laboratory to identify immediate QC failures and ensure that effective corrective actions are taken when failures are identified. Findings: 1. The laboratory did not ensure that the procedure for running quality control (QC) on the toxicology analyzer accurately reflected the current practice in the laboratory. Cross-refer to D5401 2. The laboratory did not document the date of discontinuance for written procedures that were not performed. Cross-refer to D5409 3. The laboratory failed to label toxicology controls and reagents with the date they that were opened and their expiration date. Cross-refer to D5415 4. The laboratory failed to ensure that toxicology QC and calibrators were not used after they exceeded their expiration date. Cross-refer to D5417 5. The laboratory did not ensure that all corrective actions were documented when toxicology QC was unacceptable. Cross-refer to D5783 6. The laboratory failed to ensure that written quality assurance (QA) policies were followed to monitor, and correct problems identified in the analytic phase of patient testing. Cross-refer to D5791 7. The laboratory did not have the correct name of the testing facility on the patient final report. Cross-refer to D5805 8. During an interview on 12/13/19 at 12:30 PM, the TC confirmed that the LD failed to ensure that QA and QC programs were maintained to identify failures in quality as they occur.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

	This STANDARD is not met as evidenced by: The technical consultant did not ensure that acceptable levels of analytic performance are maintained throughout the entire testing process. Cross-refer to D6022
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: The testing person did not ensure that controls and reagents for toxicology testing were not used past their expiration date. Cross-refer to D5417
D6075	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(6) Each individual performing moderate complexity testing must document all corrective actions taken when test systems deviate from the laboratory's established performance specifications. This STANDARD is not met as evidenced by: The testing person failed to document all corrective actions taken when toxicology instrument calibration failed and quality control was out of range. Cross-refer to D5783