Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	21D2142104	08/15/2018
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
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on review of laboratory test request forms and interview with the technical consultant (TC), the laboratory did not have all identifiers and information needed on the test request form when requesting and performing in house patient toxicology testing Findings: 1. The name and address of the laboratory "Providence Pain Management Center" was not on the test request form. 2. The time specimens were collected were not written on the laboratory test request by the collection person. 3. Two laboratory test request forms from collection date 5/24/18 and 5/30/18 did not have the collectors signature in the collectors box on the form. 4. The test request form did not have the definition of the "High Risk: Quantitative and Qualitative", "Mod Risk: Quantitative and Qualitative", Low Risk: Quantitative and Qualitative", "CUP POC Only", and LCMS Only" in the "lab order" section of the test request form. 5. The TC stated that the physicians will select a box for the "High Risk:

	Quantitative and Qualitative", "Mod Risk: Quantitative and Qualitative", Low Risk: Quantitative and Qualitative", "CUP POC Only", and LCMS Only" in the "lab order" section that correlates to the patient history. 6. The laboratory did not provide on the test request form when not to send for additional confirmation testing when a patient in house toxicology test is "positive". 7. The TC stated that sometimes the physicians may decide not to send a positive in house test for confirmation due to the patient history.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the technical consultant, the laboratory did not have a client service manual when urine toxicology specimens needed referral for confirmation testing. Findings: 1. The laboratory did not have a client service manual available to describe ordering, collection and submission of specimens for urine drug testing. 2. The laboratory provided qualitative testing based on clinical need. The laboratory did not have a client service manual that describes the tests making up each panel including methodology that is selected by the physician when send out for quantitative testing is performed.
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 review of the written procedure and interview with the technical consultant

	(TC), the laboratory did not establish written procedures for all areas of the laboratory when performing urine toxicology testing. Findings: 1. The laboratory did not establish a cut off range for performing qualitative toxicology testing. The laboratory final reports included a analyzer value as the toxicology result and did not state "positive" or "negative" and the final report did not include a cut off range for the drugs that were tested by the laboratory. 2. The laboratory did not establish procedures for confirming that urine specimens were not adulterated by performing the Ph, creatinine, and specific gravity. Positive in house toxicology samples are sent for quantitative testing at the request of the physician. 3. The TC stated that because they are performing a qualitative test that the laboratory did not have to ensure that urine samples were not altered. 4. The laboratory did not have step by step instructions for testing personnel to follow that included when to store specimens in the refrigerator/freezer when testing can not be performed right away, daily quality control, and send out procedures for confirmation. 5. The laboratory did not have corrective action procedures for testing persons to follow when problems occurred in the laboratory that included patient testing, daily quality control, and patient specimens that are sent for confirmation. 6. The TC stated that the laboratory has the analyzer service manual for performing patient testing but not all steps and procedures in the service manual is needed for the testing performed in house.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the chemistry analyzer service manual and interview with the technical consultant (TC), the laboratory did not document the humidity level each day testing was performed. Findings: 1. The laboratory began performing toxicology testing in April 2018. 2. The laboratory did not document each day of patient testing the room humidity level to ensure accurate and reliable testing performed on the chemistry analyzer. 3. The analyzer service manual states that optimal humidity level for performing patient testing is 20% to 80% RH with no condensation. 4. The TC stated that he was not aware that humidity level needed to be documented each day of patient testing.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on review of the written procedure manual, review of quality control errors,

	and interview with the technical consultant, the laboratory did not document corrective action procedures to include each step performed to correct the identified error and did not include the actual date corrective action procedures were performed. Findings: 1. The laboratory performs toxicology testing and had problems with the PCP quality control (QC) 5/3/18. 2. The testing person (TP) did not document on the "Quality Control Outlier Log" that the PCP QC failed. 3.. The TP stated she called the manufacturer for instructions. 4. The TP did not document on the"Quality Control Outlier Log" the time and person she spoke with for help on 5/3/18 and did not document the instructions given to her by the manufacturer for the failed PCP QC. 5. The TP did not document on the "Quality Control Outlier Log" until 5/7/18 that patient results were not reported and the manufacturer was notified for the PCP QC failure 6. The TP documented on 5/3/18 on the "Quality Control Outlier Log" that she recalibrated, and reran QC for the PCP failure 7. The recalibrating and rerunning of the PCP QC was not performed on 5/3/18. The recalibrating and rerunning of the PCP QC was actually performed on 5/7/18. 8. On 5/7/18 the PCP QC failed again. The failure was not document on the "Quality Control Outlier Log". 9. On 5/7/18 The TP documented on the "Quality Control Outlier Log" that she changed the PCP QC and the QC passed. 10. The PCP QC was not changed until 5/9/18 when it passed and there was no documentation of patient results not being reported and the manufacturer notified for the failure until 5/22/18. 11. The technical consultant confirmed that laboratory did not document corrective action procedures to include each step performed to correct the identified error on the actual date that the problem occurred.
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 review of patient final reports and interview with the technical consultant, the laboratory did not include the name of the facility where toxicology testing was performed on the final report. Findings: The laboratory began patient testing in April 2018. The laboratory name "Providence Pain Management Center" was not included on the patient final reports.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the patient final report, interview with the technical consultant

	TC), the laboratory did not maintain post analytic laboratory procedures when performing patient urine toxicology testing. Findings: 1. The TC stated that the laboratory performs a qualitative test where they only report positive or negative urine toxicology result on the patient final report. 2. Review of patient reports showed a value reported in the result section on the final report along with a normal range of -999999.9 to 99.9 for each of the seven tested drugs. 3. The TC stated that the issue with reporting an actual value on the final report was because the chemistry analyzer was set up to report a value.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the technical consultant, the laboratory director failed to establish quality assessment (QA) procedures to ensure the quality of laboratory services. Findings: 1. The laboratory director did not establish QA procedures for the preanalytic, analytic, and postanalytic areas of the laboratory to ensure accurate and reliable patient testing when performing toxicology testing. 2. The laboratory director did not have QA procedures to verify the collection and labeling of patient specimens, identifying and correcting problems, accurate and reliable patient testing, reporting results, training and competency, proficiency testing, quality control procedures, maintenance and function checks, complaints, records review, specimen handling, and storage. 3. The technical consultant confirmed that laboratory director failed to establish quality assessment procedures to ensure the quality of laboratory services.
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on review of the written procedure manual, review of quality control errors, and interview with the technical consultant, the technical consultant did not ensure that corrective action procedures documented included each step performed to correct the identified error and did not include the actual date corrective action procedures were performed. Findings Refer to D5779 The technical consultant confirmed that he did not ensure that documented corrective action procedures were reviewed to include each step performed to correct the identified error on the actual date that the problem occurred.