Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2093495	10/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Choice Pain & Rehabilitation Center	1005 N Point Blvd Suite 730, Baltimore, 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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation and interview, the lab did not ensure that biohazard and chemical waste was properly disposed. Findings: 1. At 9:00 am a paper waste basket observed by the surveyor, located within the testing area of the lab, contained a pair of blue latex gloves used during lab testing; and 2. Lab staff confirmed that the waste basket containing the gloves was not to be used as a biohazard and chemical waste container and the gloves should be disposed of in the red waste container situated at lab entrance.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with testing person, the laboratory did not ensure that there were written policies and procedures for monitoring the unacceptable urine specimens that are received into the laboratory to monitor, assess and, when indicated, correct problems identified in the postanalytic

	systems. Findings: 1. According to the testing person the laboratory has a specimen rejection log for documenting unacceptable specimens received from the satellite offices. The testing person will document the information on the specimen rejection log. Then email the satellite office that the test was canceled due to leakage or some other rejection criteria. 2. Review of the procedure manual showed that no approved instructions were provided for documenting unacceptable specimens on a log and emailing the satellite office about the cancellation of the testing. 3. During the survey on 09/17/2018 at 3:00 PM the testing person confirmed that there were no defined policies and procedures for documenting unacceptable specimens on a log and emailing the satellite office about the cancellation of the testing.
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 the procedure manual and interview with the testing person, the laboratory did not establish written procedures for the transportation of the toxicology specimens from the satellite offices to the main laboratory. Findings: 1. According to the testing person the urine samples are picked by the laboratory director and transported to the main laboratory. 2. Review of the procedure manual showed that no instructions were provided to the satellite offices that included- patient preparation; specimen collection; specimen labeling, including patient name or unique patient identifier; specimen storage and preservation; and conditions for specimen transportation. 3. During the survey on 09/17/2018 at 3:00 PM the testing person confirmed that there were no defined policies and procedures for the satellite offices to follow when collecting and transporting urine samples to the main laboratory.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on observation and interview with lab staff, the toxicology lab did not have a written service manual describing the lab services to the user. Findings: 1. It was observed that the lab did not have a client services manual describing the tests offered, also including description of test methods performed by the lab, ordering instructions, collection instructions, transport instructions and storage instructions; and 2. During interview with lab staff on the day of survey, it was confirmed that the lab did not have a client services manual.
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 observation and interview with lab staff, the toxicology lab did not have written procedures to transporting patient samples for toxicology testing. Findings: 1. The lab did not have written procedures for collection and transportation of patient urine specimens to the lab; 2. The lab written procedure states that specimens for toxicology testing must be received within three days of collection, but does not instruct lab staff on how to process specimens that exceed the three day collection requirement; 3. These findings were confirmed during interview with lab staff on the day of survey.
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 observation and interview with lab staff, the toxicology lab did not ensure test reagents were not used past expiration. Findings: 1. The lab did not record and maintain the manufacturer name, lot number and expiration date of control reagents and test reagents and chemicals used for liquid chromatography/mass spectrometry/ mass spectrometry testing, including documentation of prepared reagents from original sources and establishing expiration dates of prepared reagents; and 2. These findings were confirmed during interview with lab staff on the day of survey.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The

	laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with lab staff, the toxicology lab did not have written procedures to evaluate quality control test results. Findings: 1. The lab reviews Levey-Jennings charts to determine, over time, shifts and trends within the toxicology quality control testing; 2. The lab performs liquid chromatography/mass spectrometry/ mass spectrometry testing of patient samples, the quality control results are reported as ng/ml (quantitative numerical values); 3. During review of quality control records, lab staff stated that the lab uses an established mean and standard deviations for each analyte and each level of control to determine acceptability of control results, but during review of Levey -Jennings charts from June 2018 (for gabapentin, lorazepam, benzoylecgonine MDMA, meprobromate, morphine, hydromorphone, methadone, fentanyl and cotinine) the lab was evaluating quality control results using calculated means and standard deviations, control acceptability criteria that is variable because every time a new result is obtained, the mean and standard deviation are recalculated; 4. The labs written procedure did not include instructions for setting up and evaluation of either established or calculated (variable) methods to determine acceptability of controls and monitoring for shifts and trends; and 5. These findings were confirmed during interview with lab staff on the day of survey.
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 observation and interview with lab staff, the toxicology lab did not have written procedures to document unsatisfactory conditions of the patient specimen on the labs final report. Findings: 1. The temperature of the urine specimen collection container is recorded after the urine sample is obtained, to ensure the temperature of the specimen is consistent with a freshly collected urine sample and this temperature is recorded on the test requisition; 2. The lab did not have a written procedure to document an unsatisfactory temperature reading (indicating specimen tampering by the patient) on the final report; and 3. During interview with lab staff on the day of survey, it was confirmed that the lab did not have a written procedure to document unsatisfactory conditions of the patient specimen on the labs final report.

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 procedure manual and interview with testing person, the laboratory did not ensure that there were written policies and procedures for monitoring the transfer of data from the analyzer to the Laboratory Information System (LIS) to monitor, assess and, when indicated, correct problems identified in the postanalytic systems. Findings: 1. According to the testing person the LIS has been validated and data is printed on a regular basis to verify the transfer of data from the toxicology analyzer. 2. Review of the procedure manual showed that no approved instructions were provided for monitoring the LIS and correcting problems identified during the process. 3. During the survey on 09/17/2018 at 3:00 PM the testing person confirmed that there were no defined policies and procedures for the the verification of the LIS system and the frequency that the verification is performed.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of the validation documentation and interview with the testing person, the laboratory director did not ensure that the toxicology validation documentation included the dates of the review. Findings: 1. Review of the validation documents that included the EP Evaluator linearity regression summary, linearity summary and accuracy, reportable range and linearity reports showed that the reports were printed on November 1, 2017. The reports showed that the laboratory director had singed the report but did not include a date of review showing that they were reviewed prior to testing patient specimens. 2. During the survey on 09/17/18 at 3:00 PM the testing person confirmed that all of the toxicology validation records had not been approved by the laboratory director.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual and the testing person, the laboratory director did not ensure that there was a written protocol to follow when

	performing the validation of the Liquid Chromatography - Mass Spectrometry (LC-MS) analyzer. Findings: 1. The laboratory records showed that split samples, patient samples, and standards had been tested and evaluated to validate the LC-MS analyzer. 2. The written policies and procedures that were reviewed did not include a defined validation protocol to be followed to ensure that the minimum number of split samples, patient samples and standards were performed and found to be acceptable prior to testing and reporting patient specimens. 3. During the survey on 09/17/2018 at 3:00 PM the testing person confirmed that there was no defined protocol for the validation of the LC-MS analyzer.