Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2027353	03/12/2020
Name of Provider or Supplier	**Street Address, City, State**	
Metro Spine Laboratory	9001 Woodyard Rd Ste A, Clinton, 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
D2116	TOXICOLOGY CFR(s): 493.845(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of the toxicology proficiency testing (PT) and interview with the testing person, the laboratory failed to investigate and document remedial actions for 1 of 6 unacceptable analyte testing scores. The findings include: 1.The laboratory's "Proficiency Testing Procedure" states that "All unacceptable performances/PT failures must be investigated and corrective actions taken to prevent reoccurrence. All steps taken must be documented and included in the review by the Laboratory Director." 2.During the UDC-A 2019 PT event, sample UDC-06 tested unacceptable for methadone. The investigation worksheet for this testing event did not include an evaluation of specimen UDC-06 for methadone. 3.On 03/12/2020 at 12:45 pm, the testing person confirmed that the investigation and remedial actions were missing for the unacceptable analyte testing score.
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 procedure manual and interview with the testing person, the laboratory's standard operating procedure manual (SOPM) did not define the expiration dates of the stock solution and internal standard once they are prepared. Findings: 1. The SOPM provides instructions for the preparation of the stock solution and internal standard used for testing on the liquid chromatography with tandem mass spectrometry (LC/MS/MS) analyzer. The instructions include labeling the bottle with the solution identity and preparation date. The instructions do not define the longevity of the solution. 2. During the survey on 03/12/2020 at 12:30 PM the testing person confirmed that the SOPM did not define the longevity of the solution.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) and interview with the testing person, the laboratory failed to implement a clear corrective action plan for unacceptable PT testing results. 1.Review of the toxicology PT records for the first event, UDC-A 2019, showed that 5 analytes received unacceptable testing results. 2.A "PT Exception Investigation Worksheet" was completed documenting steps taken to investigate the root cause of all unacceptable analytes. The worksheet includes questions that have yes or no answers to evaluate possible sources of errors. If any of the answers are "no" then it is an indication of where the source of the error may have occurred. On the investigation sheet for UDC-A 2019 all questions were answered as "yes" indicating that the source of the error was not identified by the questions. 3.In the corrective action section of the worksheet it states that the samples were "rerun to check if the results were the same" and that no patient samples would have been affected due to the unacceptable PT results. 4.It is not clear on the investigation worksheet what the root causes of the unacceptable results were. It is also unclear what corrective actions were taken to ensure that the unacceptable results would not recur. 5.On 03/12/2020 at 12:45 pm, the testing person confirmed that the documentation for the investigation and corrective actions for UDC-A 2019 PT are incomplete.

D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of competency records and interview with the laboratory director (LD), the LD failed to perform competency procedures for the testing person performing toxicology testing. Findings: 1. The LD did not perform annual competency procedures for the testing person performing high complexity testing. 2. Competency procedures were performed in March 2020 and May 2019 by the laboratory consultant who is not qualified to perform high complexity toxicology testing. 3. The LD confirmed that competency procedures were not performed by her during the years 2020 and 2019.
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 review of the written procedure manual and interview with the laboratory director (LD), the LD failed to have the duties and responsibilities of all persons involved with toxicology testing. Findings: 1. The laboratory performs high complexity testing. 2. The laboratory did not have written duties and responsibilities for the LD, technical supervisor, general supervisor, nor the testing person. 3. The laboratory director confirmed that duties and responsibilities were not available for all persons involved in the lab.