Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2027353	03/22/2018
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
D2005	ENROLLMENT CFR(s): 493.801(a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. This STANDARD is not met as evidenced by: Based on review of the CASPER Report 0096D CLIA Application and Survey Summary report and interview with the laboratory director, the laboratory did not authorize the Proficiency Testing (PT) agency to release the PT results to Center for Medicare & Medicaid Services (CMS) to determine successful participation. Findings: 1. The laboratory is required to authorize PT agency to submit the PT results to CMS. The results are entered into the federal data base. These results are available to the state agency (SA) for periodic review. 2. Prior to the survey the CASPER Report 0096D CLIA Application and Survey Summary (individual laboratory profile for PT results) was pulled for review. The CASPER Report 0096D report lists the year, event number, each analyte tested in the laboratory and score for three consecutive years. The report that was pulled indicated that "No routine scores found for this provider" had been received. 3. During the survey on 02/26/18 at 1:00 PM the laboratory director confirmed that the PT results did not show up on the CASPER Report 0096D for review by the SA staff.
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 with laboratory (lab) staff, the lab did not have a written procedure following manufacturer recommendations for maintaining the filter in the lab hood. This was confirmed during interview with lab staff on the day of survey.
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 review of the procedure manual and interview the laboratory manager, the laboratory did not provide a client service manual to the satellite offices with written pre-analytical instructions for the satellite office staff to follow when submitting specimens for analysis. Findings: 1. It was observed in the written procedures that the laboratory did not have a written client service manual that includes detailed descriptions for individual tests, test panels (screening and confirmatory) and reflex (confirmatory) testing performed as part of a test panel or when individual urine drug screen results are reported positive for a urine screen. 2. The requisition did not provide the client details on test methods employed by the laboratory, performance specifications established or verified, information that may affect the interpretation of test results, specimen submission requirements and descriptions of analytes tested by the laboratory. 3. The policies and procedure manuals showed that the laboratory did not have written instructions available to the satellite offices that included patient preparation, specimen collection, specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source, specimen storage and preservation, conditions for specimen transportation, specimen processing, specimen acceptability and rejection, specimen referral and how to maintain the patient log book at the offices. 4 During there survey on 02/26/18 at 1:00 PM the laboratory manager confirmed that the laboratory did not have written pre-analytical instructions available to the satellite offices for the collection and transportation of the specimens to the main laboratory.
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 personnel and laboratory director, the laboratory did not have written policies and procedures for all required activities performed by the testing personnel. Findings: 1. During the interview the testing person stated that once the urine specimens were tested on the Mindray - Pointe Scientific toxicology analyzer they are given a new sample identification number and a pending worksheet is prepared prior to being tested on the Liquid Chromatography-Mass Spectrometry (LCMS) toxicology analyzer. 2. Review of the procedure manual showed that there were no written pre-analytical procedures for assigning the urine specimens a new identification number and preparation of a worksheet for testing on the LCMS toxicology analyzer. 3. Review of the procedure manual showed that there were no written policies and procedures for maintaining post analytical paperwork and documenting the results into the electronic medical records computer system. 4. During the survey on 02/26/18 at 1:00 PM the laboratory director confirmed that the policy and procedure manual did not contain all the required written instructions for the laboratory staff.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the product insert for "BluRapids" multi-drug test cup, laboratory worksheets and interview with the testing person who performs toxicology screening, the laboratory did not follow the manufacturers instructions for documenting "Specimen Collection and Preparation" observations. Findings: 1. The "BluRapids" product insert section labeled "Specimen Collection and Preparation" #3 states "The technician observes temperature strip affixed on the test cup between 2 to 4 minutes to see if the urine is diluted by water or liquid other than urine." The temperature range from 32 degrees Celsius - 38 degrees Celsius is acceptable. 2. The testing person confirmed that the record system did not include documentation showing that the urine was within the acceptable temperature limits prior to confirmation testing. 3. During the survey on 02/26/18 at 1:00 PM the testing person confirmed that the laboratory's record system did not include documentation showing that once the urine was collected the specimen was within the acceptable temperature range prior to confirmatory testing.
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 record review and interview with laboratory (lab) staff, the lab did not record refrigerator, freezer and room temperatures each day of testing, but instead recorded the readings on a weekly basis. Findings: 1. Temperature recordings on 2018 maintenance records were made on a weekly basis. 2. During interview with lab staff on the day of survey at 1:00 PM, staff stated that the temperature readings were recorded each week and not each day of patient testing.
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 interview with laboratory (lab) staff and review of maintenance records, the lab did not ensure reagents were not used past expiration. Findings: 1. The lab did not document solutions and water used for Liquid chromatography-mass spectrometry (LC-MS) testing of patient samples. 2. Bottles of expired reagents were in the lab freezer and included SLE working std, ISTD stock ii, D+S working internal std, all expired September 30, 2017. 3. This was confirmed during the interview with lab staff on 02/26/18 at 1:00 PM.
D5789	TEST RECORDS CFR(s): 493.1283(b) Records of patient testing including, if applicable, instrument printouts, must be retained. This STANDARD is not met as evidenced by: Based on interview with laboratory (lab) staff, the lab did not back up the calibration curves for the Liquid chromatography-mass spectrometry (LC-MS) testing that are created each day of patient testing. Findings: 1. The laboratory creates a calibration curve for each analyte tested on the LC-MS each day of testing. 2. The curve is stored on the computer hard drive associated with the LC-MS analyzer. 3. The lab does not back up the curves created each day to ensure access in the event of a problem with the computer. 4. This was confirmed during interview with lab staff on 02/26/18 at 1: 00 PM.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)

	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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory (lab) staff, the lab did not document its investigation and provide a written corrective action plan for the third toxicology proficiency test event performed in 2017. Findings: 1. The lab is enrolled in proficiency testing for urine drug testing. 2. In 2017 the lab reported morphine, bupenorphine and 6-acetylmorphine for the event identified by the proficiency test provider as UT-C. These three drugs or metabolite responses were identified as unacceptable by the proficiency test provider, who evaluated the labs performance. 3. The lab did not have a written corrective action plan that identifies the problem and provides a corrective action to ensure the problem will not reoccur. 4. This was confirmed during interview with lab staff on 02/26/2018 at 1:00 PM.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of testing personnel qualifications and interview with laboratory director, the laboratory failed to ensure that one of the testing personnel with a foreign degree met the qualification requirements of this subpart prior to performing toxicology patient testing (D6171).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical

laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on review of testing personnel qualifications and interview with the laboratory director, the laboratory failed to ensure that one of the testing personnel with a foreign degree met the qualification requirements of this subpart prior to performing toxicology patient testing. Findings: 1. The surveyor reviewed testing personnel qualifications for the personnel listed on the Laboratory Personnel Report (CLIA) (CMS-209) signed and dated on February 26, 2018 by the Laboratory Director. One testing person (TP#2) performing toxicology testing possessed an undergraduate degree from P. M. B. Gujarati Science College, Indore in India granted in 1983. 2. There was no documentation in the personnel file of TP#2, that the degree earned in P. M. B. Gujarati Science College, Indore in India granted in 1983, was ever evaluated for equivalency to that obtained from an accredited institution in the United States. 3. During the exit survey on 03/22/2018 at 9:08 AM via a phone conversation, the laboratory director confirmed that TP#2 did not have documentation showing that the degree from India had been evaluated for equivalency from an accredited

	institution in the United States.