Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2022519	07/10/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pain Physicians Ny, Pllc	240 E 23rd Street 1st Floor, New York, NY	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory's LCMS analysis records and confirmed in an interview with the laboratory technical consultant and testing personnel, the laboratory failed to save the final analysis of results after all maniputlations for the Shimadzu-8050 LCMS system from August 11, 2017 through July10, 2019. FINDINGS: 1. The laboratory testing person confirmed at approximately 3:30PM on July 10, 2019 that when he analyzes all the data and manipulates the integration and cleans up the results he does not save the final analysis document. He only saves the raw data files. 2. While it may be theoretically possible to reconstruct the data from the raw data files, it is unlikely to be successful. 3. Approximately 1800 patients results were released during this time period.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on surveyor's review of the College of American Pathologists (CAP) proficiency testing (PT) and American Proficiency Institute (API) records and confirmed in an interview with the technical/general supervisor and testing personnel,

	the laboratory failed to evaluate and verify the accuracy of the of 31 out of 75 toxicology analytes in the year 2018. FINDINGS: The technical supervisor and testing personnel, confirmed on July 10, 2019 at approximately 2:00 PM, that the laboratory failed to evaluate and verify the accuracy of the of 31 toxicology analytes in the year 2018. a. The laboratory uses the CAP modules the Urine Drug Screening (UDS) and Drug Monitoring Pain Management (DMPM) for twice year verification. The laboratory failed to verify 31 out of 75 toxicology analytes for screening and confirmatory mass spectrometry testing. 2. Approximately 1500 patients specimens were tested during this time-period
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 lack of a pre-analytic procedures for the collection and storage of urine specimens and confirmed in an interview with the technical/general supervisor and testing personnel, the laboratory failed to establish written procedures and policies for urine specimens. FINDINGS: The technical/general supervisor and testing personnel confirmed on July 11, 2019 at approximately 2:30 PM, that the laboratory failed to have written procedures for urine specimens to include: patient preparation, urine collection, verification of urine specimen, labeling of the specimen, storage and preservation, specimen acceptability and rejection and data entry of information into the electronic medical records (EMR).
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 a review of the laboratory procedure manual, pipet calibration records, and an interview with the technical supervisor and the testing persons the laboratory is not following their procedure for performing pipet calibrations every six months and does not have a procedure for twice year verification of toxicology analytes not cover by the laboratory ' s Proficiency Testing (PT) Provider. Findings: 1. At approximately 2: 30 PM on July10, 2019 the surveyor observed surveyor that the laboratory did not follow their procedure to calibrate their pipets. Pipet calibration records for 2017 and 2018 show only one calibration performed each year. 2. At approximately 3:00 PM on July 10, 2019 the testing person confirmed that the laboratory had no procedure for twice year verification for analytes not covered by the College of American Pathologist PT Program.

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 a review of the General and Toxicology Procedure manuals and an interview with the testing persons and technical consultant, the laboratory failed to have a complete procedure that encompassed in detail all the points mentioned in this standard. Findings: 1. On July 10, 2019, a review of the General Procedure Manual found a large number of procedures that did not apply to work performed in this laboratory. 2. At the same time a review of the Toxicology testing Manual was in a folder with no specific organization. The surveyor was not able to determine if all required procedures and detailed instructions were available to the testing staff. 3. Based on discussion of the procedure manuals it was clear that the testing persons were not familiar with the information contained in the procedures.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and an interview with the laboratory technical supervisor and the testing personnel, it was determined that the laboratory director failed to ensure that all components of quality control for Toxicology testing were established and performed to provide quality laboratory services. Refer to: D3031, D5403
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are

	established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of laboratory records and confirmed in an interview with the laboratory technical supervisor and the testing persons at the time of the survey, the previous laboratory did maintain an effective quality assurance program. Findings: The Director and technical supervisor failed to identify shortcomings in procedure manuals, data analysis, and follow proficiency testing requirements for twice year verification. Refer to: D3031, D5217, D5311, D5401 and D5403
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on a review of records and in an interview with the technical supervisor, the technical supervisor failed to provide proper oversight of procedure manuals, proficiency testing and analytic analysis records. Refer to: D3031, D5217, D5311, D5401 and D5403