| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 21D2049477 | 03/11/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Pain And Spine Specialists Of Maryland, Llc | 2702 Back Acre Circle, Suite 290b, Mount Airy, 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 |
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| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>I. Based on review of the standard operating procedure (SOP) manual, quality control (QC) records and interview with the laboratory director (LD), the laboratory failed to have a procedure for performing and documenting parallel testing of new QC lots for urine drug screen testing. Findings: 1. The citation from the previous survey conducted on 11/17/2022 stated that "The procedure manual did not include instructions for performing, recording, and storing results from parallel testing for new QC lots." Review of the SOP showed that the procedure submitted as part of the plan of correction failed to include the updated instructions for performing, recording, |

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| | and storing results from parallel testing for new QC lots. 2. Review of the QC records from 2023 and 2024 showed that the parallel testing of new QC lots had not been performed, maintained and reviewed to ensure that the results were acceptable. 3. During the interview on 03/11/2024 at 10:50 AM, the LD confirmed that the updated laboratory policy to perform parallel testing on new QC lots was not in the SOP and that there was no documentation showing that the testing person was performing the parallel testing when each new QC lot was started in the laboratory. II. Based on review of the QC records, SOP and interview with the LD, the laboratory failed to have written instructions for printing and scanning monthly laboratory records to the LD for review. Findings: 1. The QC records for 2023 and 2024 were reviewed. Some of the records appeared to be photocopies of the originals. When interviewed at 11:00 AM, the LD stated that at the end of the month the testing person will scan the QC, maintenance, and instrument records to the LD for review. Once the records are reviewed they are returned to the office via email, printed and included in the appropriate log book. 2. Review of the SOP showed that there were no written instructions for scanning monthly laboratory records to the LD for review. 3. During the exit interview on 03/11/2024 at 11:35 AM, the LD confirmed that the SOP failed to include written instructions for scanning monthly laboratory records to the LD for review. III. Based on observation, the patients requisition, SOP and interview with the testing person (TP) and LD, the laboratory failed to have written instructions for entering accurate patient information into the laboratory information system (LIS). Findings: 1. During the survey at 11:00 AM. the TP was observed entering the patient information into the LIS. The requisition showed that the specimen was collected on 03/08/2024 and received in the laboratory on 03/11/2024. The TP was observed entering the collection date as 03/11/2024 and entering their initials and not the actual collection date and initials of the collector. When interviewed the TP stated that those were the instructions given when he was trained and there were no written instructions for entering patient information into the LIS. 2. Review of the SOP at the time of the survey showed that there were no written instructions for how to enter patient information into the LIS. 3. During the exit interview on 03/11/2024 at 11:35 AM, the LD confirmed that the SOP failed to include written instructions for entering the actual collection date and initials listed on the requisition form. |
| **D6021** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>I. Based on review of the standard operating procedure (SOP) and interview with the laboratory director (LD), the LD failed to provide a quality assurance (QA) procedure that included written instructions for proficiency testing (PT) enrollment, documentation and storage of the results, documentation and corrective actions to be taken when PT results were found to be unacceptable. Findings: 1. Review of the QA SOP showed that there was no reference to the enrollment in an approved PT program, documentation and storage of the results, documentation and corrective actions to be taken when PT results were found to be unacceptable. 2. During the |

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| | interview on 03/11/2024 at 10:50 AM, the LD confirmed that the QA SOP failed to include comprehensive PT policies and procedures for the testing person to follow. II. Based on review of the patients final report, requisition, the SOP and interview with the testing person (TP) and LD, the LD failed to ensure that the final report included the accurate collection date and initials of the collection person and the correct initials of the TP. Findings: 1. Review of a patient's final report and requisition showed that the collection date was being entered as the received date into the laboratory information system (LIS). The initials of the collection person were being entered as the initials of the TP. Cross refer to D5403 #3 for additional details. 2. The initials listed on the final report are "NR" and the initials of the current TP are "GR." When interviewed, the TP confirmed that the initials listed on the final report are those of the previous TP who left the lab in October 2022. The new TP started working in October of 2022 after the previous TP left and the LIS was not updated with the initials of the current TP. 3. During the exit interview on 03/11/2024 at 11:35 AM, the LD confirmed that the SOP failed to include written instructions for entering the actual collection date and initials listed on the requisition form and that the LIS had not been updated with the current TP's initials. |