Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2049477	06/22/2026
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the current laboratory director (LD), the previous LD failed to attest to the routine integration of PT samples into the patient workload using the laboratory's routine methods in three of three PT events reviewed. Findings: 1. Records for three PT events from 2024-2025 were reviewed. 2. The previous LD, who was also the technical consultant, did not sign the forms attesting that PT samples were tested in the same manner as patient specimens for all three PT events reviewed. 3. During the exit interview on 06/22/2026 at 2:25 PM, the current LD confirmed that the previous LD didn't attest to the routine integration of PT samples into the patient workload in three of three PT events.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the current laboratory director (LD), the previous LD failed to document the review and evaluation of PT results in two of three PT events reviewed. Findings: 1. Records for

	three PT events from 2024-2025 were reviewed. 2. There was no documentation that the previous LD reviewed or evaluated the PT results in two of three PT events reviewed (2024-B and 2025-B). 3. During the exit interview on 06/22/2026 at 2:25 PM, the current LD confirmed that the previous LD didn't document that the PT results from two of three PT events were reviewed and evaluated.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) (b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the current laboratory director (LD), the laboratory failed to perform a self-evaluation of scores that were ungraded by the PT provider in three of three PT events reviewed. Findings: 1. The laboratory was enrolled in PT for Urine Drug Adulterant with College of American Pathologists (CAP). 2. The following codes were used when a PT sample was not graded by CAP with the following instructions from the "Actions Laboratories Should Take when a PT Result is Not Graded" section included in CAP's participant summary. a. "[26] Educational Challenge:" "Review participant summary for comparative results and document performance accordingly. Evaluation criteria are not established for educational challenges. Laboratories should determine their own evaluation criteria approved by their laboratory director for self-evaluation." b. "[42] No credit assigned due to absence of response:" "The laboratory is required to submit results for all challenges within that test or use an appropriate exception code or indicate test not performed/not applicable/not indicated. Exceptions may be noted in the kit instructions and/or the result form. Document corrective actions to prevent future failures." 3. The analytes "Creatinine qual" and "pH qual" were not graded due to code [26] in all three PT events reviewed. 4. The analyte "Oxidants" was not graded due to code [42] for two of three PT samples in the 2025 2nd PT event. 5. There was no documentation that the laboratory performed a self-evaluation for any of the ungraded PT results. 6. During the exit interview on 06/22/2026 at 2:25 PM, the current LD confirmed that there was no documentation that the laboratory self-evaluated PT scores that were not graded by the PT provider.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the procedure manual, review of the specimen rejection log, and interview with testing person #1 (TP#1) and the laboratory director (LD), the laboratory failed to notify the submitting facilities, as stated in the procedure manual,

	when urine specimens were rejected for urine drug screen testing. Findings: 1. The laboratory performed urine drug screen testing. 2. Urine specimens were received from multiple clinic locations. 3. Specimen rejection criteria were listed in two procedures. 4. The "Urine Specimen Collection for Toxicology Testing" procedure stated that "The laboratory will notify the submitting clinic regarding rejected specimens." 5. The "Standard Operating Procedure for the Receipt and Processing of Specimens" stated to "Document problem on requisition and notify client ASAP that the specimen has been rejected" and then "Document problem and reason for rejection in Problem log book." 6. The specimen rejection log listed the specimen accession numbers, dates of receipt, and reasons for rejection. 7. During the survey on 06/22 /2026 at 2:00 PM, TP#1 stated that the laboratory didn't notify the submitting clinic for any of the rejected specimens that were documented on the specimen rejection log. They only notified the submitting clinic if they received a call for the status of a patient specimen result. 8. During the exit interview on 06/22/2026 at 2:25 PM, the LD confirmed that the laboratory didn't notify the submitting clinics when patient specimens were rejected for testing as stated in the procedure manual.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 review of the procedure manual and interview with testing person #1 (TP#1) and the laboratory director (LD), the laboratory failed to ensure that the approved procedure matched laboratory practice for documenting new quality control (QC) reagent lot numbers and expiration dates. Findings: 1. The laboratory performed urine drug screen testing using the Indiko Plus chemistry analyzer. 2. The laboratory validated new QC reagent lots by testing them in parallel with the current QC reagent lots prior to using for patient testing. 3. The "Reagent Preparation" procedure stated that "The new Quality Control Lot, after successfully passing the above test, can be used when the old lot is discarded. Remember to update the new lot number into Indiko when the lot numbers are switched." 4. During the survey on 06/22/2026 at 1: 30 PM, TP#1 stated that new QC lot numbers and expiration dates were not entered into the Indiko Plus analyzer. They then demonstrated how the lot numbers and expiration dates were entered into the laboratory information system, LABDAQ. 5. During the exit interview on 06/22/2026 at 2:25 PM, the LD confirmed that the written procedure for documenting new QC reagent lot numbers and expirations dates was outdated and there was no approved written procedure for the current practice of documenting the information into LABDAQ.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and

	This STANDARD is not met as evidenced by: Based review of proficiency testing (PT) records and interview with the current laboratory director (LD), the previous LD failed to review and evaluate PT results in two of three PT events and investigate unacceptable PT scores in one of three PT events. Findings: 1. Records for three PT events from 2024-2025 were reviewed. 2. There was no documentation that the previous LD reviewed or evaluated the PT results in two of three PT events reviewed (2024-B and 2025-B). Cross-refer to tag D5211 for details. 3. The laboratory received PT scores of 33% for the analytes "creatinine quant," "pH quant," and "oxidants" in the 2025-B event. There was no investigation into the unacceptable results or documentation of corrective actions taken. 4. During the exit interview on 06/22/2026 at 2:25 PM, the current LD confirmed that the previous LD didn't document review of PT results in two of three events and didn't ensure corrective actions were taken for failed PT results in one of three events.