Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2049477	11/17/2022
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
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 the laboratory director (LD), the laboratory failed to have an eyewash in the area where testing was performed. Findings: 1. It was observed that the area where testing was performed did not contain an eyewash to aid in flushing out the eyes of testing personnel should they be splashed with patient specimens, cleaning solutions, or testing reagents. 2. During the survey on 11/17/2022 at 1:20 PM, the LD confirmed that an eyewash was not located in the area where testing was performed.
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 review of the procedure and "Turn Around Time" reports and interview with the laboratory director (LD), the laboratory failed to ensure that specimens received

	into the laboratory beyond defined stability limits were not tested. Findings: 1. The laboratory performed specimen validity and urine drug screen testing. 2. The "Specimen Requirements" section of the procedure titled "Urine Drugs of Abuse and Adulterants Using the Thermo Reagents on the Indiko" stated that "Urine samples may be stored up to 7 days unrefrigerated. After 7 days, specimens should be stored frozen." 3. The laboratory tracked turnaround times (TAT) by running monthly reports that recorded the average TAT from collection date and received date. 4. The LD stated that all specimens were shipped, received, and stored unrefrigerated. 5. The TAT report for 09/2021 recorded the average TAT from the received date minus the collection date as 169.69 hours for specimen validity testing and as 168.72 hours for urine drug screen testing, both beyond the 7 days (168 hours) stability stated in the procedure. 6. The TAT report for 10/2021 recorded the average TAT from the received date minus the collection date as 223.49 hours for specimen validity testing and as 222.74 hours for urine drug screen testing, both beyond the 7 days (168 hours) stability stated in the procedure. 7. During the survey on 11/17/2022 at 1:20 PM, the LD confirmed that specimens were received and tested beyond defined specimen stability limits in 09/2021 and 10/2021.
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 quality control (QC) parallel testing binder, the QC records and the procedure manual and interview with the laboratory director (LD), the laboratory failed to have a procedure for performing parallel testing of new QC lots for urine drug screen testing. Findings: 1. The laboratory stored instrument printouts for new QC lots that were parallel tested against current QC lots in a QC parallel testing binder (binder). 2. Monthly summaries of three lots each of 6-acetylmorphine (6-AM) high and low QC results were reviewed. 3. Only one of the three lots had instrument printouts for parallel testing performed with current QC lots located in the binder and a search in the laboratory information system did not find any record of QC parallel testing being performed on the other two lots. 4. The procedure manual did not include instructions for performing, recording, and storing results from parallel testing for new QC lots. 5. During the survey on 11/17/2022 at 1:20 PM, the

	LD confirmed that it is laboratory policy to perform parallel testing on new QC lots, that there was no procedure for performing parallel testing for new QC lots, and that parallel testing for two of three new 6-AM QC lots was not performed.
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 review of the analyzer product specifications brochure and laboratory records and interview with the laboratory director (LD), the laboratory failed to monitor humidity in the laboratory where urine drug screen testing was performed. Findings: 1. The laboratory performed urine drug screen testing using a Thermo Fisher Scientific Indiko Plus analyzer. 2. The analyzer product specifications brochure (N12835_04 12/2017) stated "Operating temperature range of 18-30 C, humidity 40-80% (non-condensing)." 3. Laboratory records did not include documentation of humidity. 4. During the survey on 11/17/2022 at 1:20 PM, the LD confirmed that humidity was not being monitored in the laboratory where the Indiko Plus analyzer was operated.