

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2049477	(X3) Date Survey Completed 03/15/2018
Name of Provider or Supplier Pain And Spine Specialists Of Maryland, Llc	Street Address, City, State 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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with lab staff, the lab did not document the handling, preparation, processing, examination, and each step in the testing and reporting of results for proficiency testing samples, and did not .maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results for a minimum of two years from the date of the proficiency testing event. Findings: 1. The lab did not have records for the 2016 PA Department of Health proficiency test records for event 1 or event 2; 2. The lab did not have the DAI-A 2016 proficiency test work records and attestation; 3. The lab did not have the DAI-B 2016 analyzer printouts; 4. The lab did not have documentation of the directors review for the DAI-B 2017 proficiency test event; and 5. This was confirmed during interview with staff on the day of survey.</p>
D5317	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d)</p>

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 record review and interview with lab staff, the lab did not have a client service manual. Findings: 1. The lab did not have a client service manual available to clients to describe ordering, collection and submission of specimens for urine drug screening; 2. The lab provides panels or groups tests based on clinical need, but the lab did not have a client service manual that describes the tests making up each panel including methodology.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:
Based on review of the written procedure manual, interview with the laboratory director, and the testing person, the laboratory director did not approve all laboratory procedures and did not update the urine testing procedure for performing toxicology testing. Findings: A. 1. The testing person performed laboratory testing using a packet of procedures that was not reviewed and signed by the laboratory director prior to performing patient testing. 2. The packet included training manual for the analyzer, Lad Daq software for patient data, accepting controls, running patient samples, monthly and weekly maintenance. 3. The testing person stated that he had his own packet of procedures that he followed for patient testing. B. 1. The laboratory did not update the procedure for storing patient urine samples when testing was not performed immediately. 2. The written procedure did not state the length of time urine samples can be maintained frozen prior to patient testing. 3. The testing person stated that they no longer freeze urine specimens because samples are sent out for testing when Inoue testing is not performed. 4. The laboratory director stated that he did not update the written procedure when urine samples no longer needed to be frozen.

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 record review and interview with lab staff, the lab did not follow manufacturer instructions to determine acceptability of quality control results. Findings: 1. The heroin metabolite (6-AM) reagent insert from the manufacturer states that the lab is to test a positive and negative control. The manufacturer also states that the base assesment of the quality control results should be within specified limits and that the lab must monitor shifts and trends. Lab staff stated that they only check to see

that the control result is above the cutoff for a positive result and that the negative control result is below the cutoff. The mean of each control floats month to month and lab staff stated that the ranges assigned to the control results are not monitored to ensure they fall within the labs range and are not monitored for shifts or trends; 2. The lab did not have written procedures to monitor quality control means from month to month; 3. the lab did not have procedures to establish its own control ranges as stated by the manufacturer; 4. The lab did not provide package inserts for the other drugs it is screening; and 4. This was confirmed during interview with the director on the day of survey

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 written procedure manual, interview with the laboratory director, and the testing person, the laboratory did not document the room temperature each day of patient testing. Findings: 1. The laboratory did not document the room temperature during patient testing prior to October 2017 to ensure the optimal performance of the toxicology analyzer. 2. The laboratory director stated that he was unaware that the room temperature needed checking. 3. The laboratory did not have the instrument operators manual to ensure that preventative and daily maintenance procedures were performed to maintain the operating functions of the analyzer.

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of written procedures and interview with lab staff, the lab did not have written procedures to evaluate toxicology quality control test results. Findings: 1. The lab did not have written procedures to determine acceptability of quantitative quality control results for creatinine, Ph and oxidants testing for urine drug screens; and 2. This was confirmed during interview with lab staff on the day of survey.

D5801

TEST REPORT

CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

Based on observation and interview with lab staff, the lab director did not ensure that the quality control and quality assessment programs to check the interface between the laboratory information system and the clinical electronic record is satisfactory whenever updates are applied or changes are made due to problems. Findings: 1. The laboratory uses an information system to document patient test results and the test results are transferred to a clinical record using a different information program; 2. The lab did not have a written procedure to check the interface between the two information systems to ensure data is transferred in an accurate and reliable manner, after updates are made to the either the lab or clinical information systems; and 3. This was confirmed by interview with lab staff on the day of survey.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on review of the patient final report, interview with the laboratory director, and the testing person, the laboratory did not maintain post analytic laboratory procedures when performing patient urine toxicology testing. Findings: 1. The laboratory director stated that they perform a qualitative test where they only report positive or negative urine toxicology result on the patient final report 2. Review of patient reports during the year 2016-2018 showed a value reported in the result section on the final report. 3. The laboratory director stated that the issue with reporting an actual value was an information technology problem 4. The laboratory director stated that physicians does not pay attention to the value reported on the patient final report.