

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2016617	(X3) Date Survey Completed 02/15/2022
Name of Provider or Supplier Advanced Spine And Pain, Llc	Street Address, City, State 2 8th Street, Hammonton, NJ	
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 surveyor review of the Proficiency Testing (PT) records and interview with the Technical Supervisor (TS), the laboratory failed to maintain Attestation Statements (AS) signed by the Laboratory Director for Toxicology tests performed with the College of American Pathologists (CAP) in 2020 and 2021. The findings include: 1. There was no AS for CAP - Toxicology for event UT-B and UT-A 2021. 2 . The TS confirmed on 2/15/22 at 10:15 am that the laboratory did not maintain complete records for PT.</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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.</p>

	<p>This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Technical Supervisor (TS), the laboratory failed to retain all QC records for tests performed on the Carolina CLC/800 from January 5/21/19 to the date of survey. The finding includes: 1. All Toxicology QC that was repeated due to a failed QC run were not retained. 2. The TS confirmed on 2/15/22 at 11:00 am that the all QC records were not retained.</p>
<p>D5217</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Biannual Assessment (BA) records and interview with the Technical Supervisor (TS), the laboratory failed to verify the accuracy and reliability of Toxicology testing twice a year in the calendar years 2020 and 2021. The finding includes: 1. BA was performed once in 2020 and 2021. 2. The TS confirmed on 2/15/22 at 11:30 am that the laboratory did not verify the accuracy of Toxicology twice a year.</p>
<p>D5417</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of the Calibration (Cal) material and interview with the Technical Supervisor (TS), the laboratory retained expired Cal for tests performed on the Carolina CLC/800 from 5/31/21 to the date of survey. The findings include: 1. DRI (Trademark) MultiDrug Urine Drugs of Abuse Calibrator 2 Lot # 73955420 expired 5/31/21. 2. DRI (Trademark) MultiDrug Urine Drugs of Abuse Calibrator 1 Lot # 74168821 expired 12/31/21. 3. Approximately 40,000 patients run and reported. 4. The TS confirmed on 2/15/22 at 1:32 pm that the laboratory the laboratory used calibration material after its expiration date.</p>
<p>D6091</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii)</p> <p>The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Supervisor (TS) the Laboratory Director (LD) failed to ensure that</p>

Toxicology PT performed with the College of American Pathologists (CAP) was reviewed and evaluated by the appropriate staff for events A and B in 2021. The TS confirmed on 2/15/22 at 10:45 am that the LD did not ensure review and evaluation of PT events listed above.

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 the Quality Control (QC) records and interview with the Technical Supervisor (TS), the Laboratory Director failed to ensure that the laboratory maintained a QC program from 5/21/19 to the date of the survey. The findings include: 1. The monthly QC report QC lot numbers did not match the QC lot numbers used in the date ranges on the monthly QC report. 2. The QC lot numbers in the Carolina CLC/800 analyzer were not changed when new lots were put into use. 3. There was no Corretive action log for failed QC run on the Carolina CLC/800. 4. Work records for failed QC wer not maintained for QC run on the Carolina CLC/800. 5. The TS confirmed on 2/15/22 at 1:00 pm the laboratory did not ensure a QC program was maintained.