

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2016617	(X3) Date Survey Completed 05/21/2019
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
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Technical Supervisor (TS), the laboratory failed to retain the attestation record for the Chemistry Miscellaneous 2-2018 PT event performed with the American Proficiency Institute. The TS confirmed on 5/21/19 at 1:00 pm that the laboratory failed to retain all PT records.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records, review of the personnel files and interview with the Technical Supervisor (TS), the laboratory failed to perform a CA on one of one TS from March 2018 to the date of the survey. The TS confirmed on 5/21/19 at 12:20 pm that a CA was not performed on the TS.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other</p>

supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on surveyor observation of the Quality Control (QC) material and interview with the Technical Supervisor (TS), the laboratory failed to put new expiration dates on all controls used for urine Toxicology tests performed on the Carolina CLC/800 analyzers from March 2018 to the date of survey. The TS confirmed on 5/21/19 at 1:00 pm the laboratory failed to put new expiration dates on the control material.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on surveyor review of Performance Specification (PS) records and interview with the Technical Supervisor (TS), the laboratory failed to ensure that PS procedures for all urine toxicology tests performed on the Carolina CLC/800 #1 were performed prior to patient testing from March 2018 to the date of survey. The findings include: 1. A review of the PS records revealed accuracy, precision, and linearity were not performed for: a. Benzodiazepines b. Buprenorphine c. Cocaine Metabolite d. Methadone - 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) e. Opiates f. Oxycodone 2. The TS confirmed on 5/21/19 at 1:15 pm that PS were not performed on the drugs listed above.

D5439

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control

materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
Based on lack of Calibration Verification (CV) records and interview with the Technical Supervisor (TS), the laboratory failed to perform and document CV procedures at least once every six months for Toxicology Testing on the Carolina CLC /800 analyzer in the calendar year 2018 and 2019. The TS confirmed on 5/21/19 at 12:00 pm CV was not performed every six months.

D5469

CONTROL PROCEDURES
CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on surveyor review of Quality Control (QC) records, Manufacturers Package Inserts (MPI) and interview with Technical Supervisor (TS), the laboratory failed to establish the statistical parameters and verify the QC material before use for urine Toxicology tests from March 2018 to the date of the survey. The findings include: 1. The Buprenorphine QC MPI stated the control material was to be used with the Immunalysis Buprenorphine Urine Enzyme Immunoassay but the laboratory did not use that Immunoassay reagent. 2. A lack of QC documentation revealed a QC range was not established or verified before using the control. 3. The TS confirmed on 5/21/19 at 12:30 pm that the laboratory did not establish statistical parameters for Buprenorphine QC.

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

	<p>This STANDARD is not met as evidenced by: Based on surveyor review of the Laboratory Records and interview with the Technical Supervisor (TS), the laboratory failed to perform and document comparison studies for the two Carolina CLC/800 analyzers twice per year from March 2018 to the date of the survey. The TS confirmed on 5/21/19 at 12:20 pm that the laboratory did not do comparison studies.</p>
<p>D5791</p>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Quality Control (QC) records and interview with the Technical Supervisor (TS), the laboratory failed to establish a procedure to verify new QC material used in Toxicology screening tests before putting it in use from March 2018 to the date of the survey. The TS confirmed on 5/21/19 at 12:10 pm the laboratory did not have a procedure to verify new QC material.</p>
<p>D5805</p>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) and interview with the Technical Supervisor (TS), the laboratory failed to report Urine Drug confirmation test results accurately from March 2018 to the date of survey. The finding includes: 1. The laboratory performed non Food and Drug Administration cleared tests and there was no statement stating the test had not been cleared or approved by the U.S. Food and Drug Administration" on the FR. 2. The TS confirmed on 5/21/19 at 1:00 pm that Urine Drug confirmation tests were not reported accurately.</p>
<p>D6074</p>	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(5)</p> <p>Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director.</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 Testing Personal (TP) failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests performed on the two Carolina CLC/800 analyzers from March 2018 to the date of the survey. The TS confirmed on 5/21/19 at 12:45 pm that trends and shifts were not reviewed.

D6086

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:
a. Based on surveyor review of the Performance Specification (PS) records and interview with the Technical Supervisor (TS), the Laboratory Director (LD) failed to sign PS records for the two Carolina CLC/800 analyzers from March 2018 to the date of survey. The TS confirmed on 5/21/19 at 1:10 pm that the PS records were not signed. b. Based on surveyor review of the PS records and interview with the TS, the LD failed to ensure that PS were adequate to perform urine Toxicology confirmation tests on the AbSciex Triple Quad 4500 from March 2018 to the date of survey. The findings include: 1. The laboratory failed to perform a sample stability study beyond five days and room temperature. 2. There was no validation performed to establish the expiration date of reagents, working solutions, Internal Standard, controls and calibrators used. 3. The Interference study for Ketamine failed the accuracy and persicion accessment for Quality Control Level 1, 2 and 3. 4. The validation of the hydrolysis control did not include validation of: a. Temperature of the Heat Block b. Time on the Heat Block 5. The TS confirmed on 5/21/19 at 12:30 pm that PS tests were not adequate.

D6091

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(iii)

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.

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 failed to ensure that the 2-2018 Chemistry - Miscellaneous PT event for toxicology performed with the American Proficiency Institute was reviewed and evaluated by the appropriate staff. The TS confirmed on 5/21/19 at 11:45 am that the LD did not ensure all PT reports were reviewed.