

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 03D2225610	<b>(X3) Date Survey Completed</b> 06/25/2024
<b>Name of Provider or Supplier</b> Advanced Spine And Pain Llc	<b>Street Address, City, State</b> 2525 W Greenway Rd Ste 125, Phoenix, AZ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> 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 lack of manufacturer's package inserts presented for review for testing performed on the Indiko Plus analyzer and interview with the testing personnel (TP-1), the laboratory failed to retain the manufacturer's package inserts for at least 2 years for each lot of Quality Control (QC) used on the analyzer. Findings include: 1. The laboratory began patient testing in August 2021 and reports approximately 46,200 urine drug screen tests annually utilizing the Indiko Plus analyzer. 2. During the survey conducted on 6/25/2024, no evidence was presented for review to indicate the laboratory retained the manufacturer's assay information sheets for at least 2 years for each lot of QC used on the Indiko Plus analyzer. 3. The TP-1 interviewed on 6/25/2024 at 11:20 AM confirmed the laboratory failed to retain the manufacturer's assay information sheets for at least 2 years for each lot of QC and test reagent material used on the analyzer indicated above.</p>
<b>D5407</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with</p>

the testing personnel (TP-1), the laboratory failed to have the current laboratory director approve, sign and date test procedures before use. Findings include: 1. The current laboratory director indicated in the CLIA Federal Database and assigned on the CMS-209, Laboratory Personnel Form presented for review during the survey has been serving as laboratory director since 7/1/2022. 2. The policy and procedure manual presented for review during the survey conducted on 6/25/2024 was not approved, signed and dated by the current laboratory director. 3. The TP-1 interviewed on 6/25/24 at 11:40 AM confirmed that the policy and procedure manual indicated above was not approved, signed and dated by the current laboratory director. 4. The laboratory performs urine drug screens under the subspecialty of Toxicology with an annual test volume of 46,200.

**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 review of the laboratory's quality control (QC) records, lack of QC lot correlation documentation and interview with the testing personnel (TP-1), the laboratory failed to verify the criteria for acceptability of quality control materials. Findings include: 1. The laboratory began patient testing in August 2021 performing a semi-quantitative urine drug screen test on the Indiko Plus analyzer, with a reported annual test volume of 46,200. 2. No documentation was presented for review to indicate the laboratory verified the criteria for acceptability of each lot of control material used on the analyzer indicated above from August 2021 through the date of the survey on 6/25/2024. 3. The number of QC lots used on the analyzer from August 2021 through the date of the survey could not be determined at the time of the survey. 4. The TP-1 interviewed on 6/25/2024 at 11:20 AM confirmed the laboratory failed to verify the criteria for acceptability of quality control materials used on the Indiko Plus analyzer.