

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  36D2280918	<b>(X3) Date Survey Completed</b>  10/23/2023
<b>Name of Provider or Supplier</b>  Advanced Pain & Spine Institute	<b>Street Address, City, State</b>  5405 Dupont Circle, Suite A, Milford, OH	
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>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #1, the laboratory failed to enroll in a proficiency testing (PT) program for the subspecialty of Toxicology. This deficient practice had the potential to affect 19,800 patients tested under the subspecialty of Toxicology from 07/01/2023 through 10/18/2023. Findings Include: 1. The laboratory failed to enroll in a PT program for the subspecialty of Toxicology. (Refer to D2001)</p>
<b>D2001</b>	<p><b>ENROLLMENT</b> CFR(s): 493.801(a)(1)(2)(i)</p> <p>The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS;</p>

This STANDARD is not met as evidenced by:  
Based on record review and an interview with Testing Personnel (TP) #1, the laboratory failed to enroll in a proficiency testing (PT) program for the subspecialty of Toxicology. This deficient practice had the potential to affect 19,800 patients tested under the subspecialty of Toxicology from 07/01/2023 through 10/18/2023. Findings Include: 1. Review of the "Advanced Pain & Spine Institute" policies and procedures, signed and dated by the Laboratory Director on 06/02/2023 failed to find policies and procedures for PT. 2. The inspector requested the 2023 PT records for Toxicology from TP #1. 3. TP #1 confirmed the laboratory was not enrolled with an HHS approved PT provider for the subspecialty of Toxicology and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 10/18/2023 at 11:15 AM.

**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 record review and an interview with Testing Personnel (TP) #1, the laboratory failed to include in their policies and procedures the toxicology requirements for specimen processing and referral, criteria for specimen acceptability and rejection, step-by-step performance of the procedure, interpretation of the results based on the manufacturer's instructions, limitations in the testing, the laboratory's system for entering and reporting the results in the patient record and the laboratory's course of action to take if a test system becomes inoperable. This deficient practice had the potential to affect 19,800 patients tested under the subspecialty of Toxicology from 07/01/2023 through 10/18/2023. Findings Include: 1. Review of the "Advanced Pain & Spine Institute" policies and procedures, signed and dated by the Laboratory Director on 06/02/2023 failed to find policies and procedures for the toxicology requirements for specimen processing and referral, criteria for specimen acceptability and rejection, step-by-step performance of the procedure, interpretation of the results based on the manufacturer's instructions, limitations in the testing, the laboratory's system for entering and reporting the results in the patient record and the laboratory's course of action to take if a test system becomes inoperable. 2. A review of the laboratory's documentation found the manufacturer's instructions, "Indiko Plus Quick

Guide", provided on the day of inspection; however, review of this manual failed to find evidence it was reviewed, approved, signed, and dated by the Lab Director prior to implementation. 3. Further review of the manufacturer's instructions, "Indiko Plus Quick Guide", provided on the day of inspection, failed to find information that fulfilled the required regulation for a procedure manual regarding specimen processing and referral, criteria for specimen acceptability and rejection, step-by-step performance of the procedure, interpretation of the results based on the manufacturer's instructions, limitations in the testing, the laboratory's system for entering and reporting the results in the patient record and the laboratory's course of action to take if a test system becomes inoperable. 4. The inspector requested policies and procedures for the toxicology requirements for specimen processing and referral, criteria for specimen acceptability and rejection, step-by-step performance of the procedure, interpretation of the results based on the manufacturer's instructions, limitations in the testing, the laboratory's system for entering and reporting the results in the patient record and the laboratory's course of action to take if a test system becomes inoperable from TP #1. TP #1 confirmed the laboratory did not have a policy and procedure for the above listed requirements and was unable to provide the requested documentation on the date of inspection. The interview occurred on 10/23 /2023 at 12:30 PM.

**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 record review, direct observation, and an interview with the Testing Personnel (TP) #1, the laboratory failed to define criteria, monitor, and document room temperature and humidity for accurate and reliable test system operation. This deficient practice had the potential to affect 19,800 patients tested under the subspecialty of Toxicology from 07/01/2023 through 10/18/2023. Findings include: 1. A review of the manufacturer's performance specifications for the Indiko Plus chemistry analyzer revealed the following statements: "Operating temperature range of 18 - 30C, humidity 40-80% (non-condensing)" 2. Review of the laboratory's 2023 "Ambient Air Temperature Check" record, found daily laboratory room temperatures recorded, however no daily laboratory humidity was recorded. 3. Direct observation of the laboratory on the date of inspection revealed no thermometer was present in the laboratory for measuring ambient air temperature and humidity. 4. The inspector requested to see the thermometer used to monitor the laboratory ambient air temperatures, and documentation of room humidity from TP #1. 5. TP#1 stated the facility thermostat located down the hall from the laboratory was used for the laboratory ambient air temperatures, the humidity of the laboratory was not monitored and recorded, and was unable to provide the requested documentation on the date of inspection. The interview occurred on 10/18/2023 at 1:00 PM. %; percent C; degrees Celsius

**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 record review and an interview with Testing Personal (TP) #1, the laboratory failed to document all assessment activities of an ongoing mechanism to monitor, assess, and correct problems identified in the post analytic systems. This deficient practice had the potential to affect 19,800 patients tested under the subspecialty of Toxicology from 07/01/2023 through 10/18/2023. Findings Include: 1. Review of the "Advanced Pain & Spine Institute" policies and procedures, signed and dated by the Laboratory Director on 06/02/2023 found no mention of documenting assessment activities of an ongoing mechanism to monitor, assess, and correct problems identified in the post analytic systems. 2. Further document review did not find any written assessment activities of an ongoing mechanism to monitor, assess, and correct problems identified in the post analytic systems. 3. The inspector requested post analytic quality assurance documentation from TP #1. TP #1 stated the post analytic assessment activities were completed but not documented and was unable to provide the requested information on the date of inspection. The interview occurred on 10/18/2023 at 2:00 PM.