

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2190912	<b>(X3) Date Survey Completed</b>  08/19/2024
<b>Name of Provider or Supplier</b>  Spine And Wellnes Centers Of America	<b>Street Address, City, State</b>  405 S 21st Ave, Hollywood, FL	
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>D0000</b>	A recertification survey conducted on 08/19/2024 found the SPINE AND WELLNESS CENTERS OF AMERICA clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
<b>D5217</b>	<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 record review and technical supervisor (TS) interview, the laboratory failed to verify the accuracy of testing method at least twice annually for 11 out of 11 analytes tested in urine toxicology screening test at least from October 2022 to August 2024. Findings included: -Review of the test menu provided with the FORM CMS-116 Clinical Laboratory Improvement Amendment (CLIA) Application for Certification signed by the Laboratory Director on 08/13/2024 indicated that the urine screening test included the following analytes: Amphetamine, Benzoylcegonine, Buprenorphine, 3,4-Methylenedioxymethamphetamine (MDMA), methadone, Morphine, Oxazepam, Oxycodone, Phencyclidine, Secobarbital and Tetrahydrocannabinol (THC). -Review of Proficiency testing records revealed that the laboratory failed to perform the twice a year accuracy verification for the screening test. -The laboratory tested 3,525 patients from October 2022 to August 2024. During an interview on 08/19/2024 at 12:00 PM with TS, she confirmed that the laboratory failed to do twice a year verification for the screening test for the analytes listed above.</p>