

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1087316	(X3) Date Survey Completed 03/28/2019
Name of Provider or Supplier Spinecare Associates Llc D/B/A Florida Spine	Street Address, City, State 2250 Drew St Ste 2, Clearwater, FL	
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
D5217	<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 of proficiency testing and split sample testing and interview with the Head of Auxiliary Services, the laboratory failed to verify twice annually all drugs (except for tapentadol) in the laboratory's panel for 2 out of 2 years reviewed (2017-2018). Findings included: Review of the College of American Pathologists (CAP) proficiency testing records for two out of two years (2017-2018) revealed that the CAP proficiency testing, tested each drug in the panel once per year except phencyclidine (PCP) and 3,4 - Methylenedioxymethamphetamine (MDMA) which were not included in the CAP proficiency testing. For two out of two years (2017-2018) PCP and MDMA were not tested by CAP proficiency testing. All other drugs were included in the CAP proficiency testing once per year. Interview on 03/28/2019 at 11:45 AM with the Head of Auxiliary Services confirmed that the CAP proficiency testing did not include a challenge for each drug twice annually for two out of two years (2017-2018).</p>
D5791	<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>

This STANDARD is not met as evidenced by:

Based on record review and interview with the Head of Auxiliary Services, the laboratory failed to have an effective quality assurance (QA) program that identified or corrected problems for quality control for two out of two years (2017-2018) reviewed. Findings Included: Review of the quality assurance monthly checklist revealed that the laboratory did not define the shift; indicate the name of the drug for which an issue was identified, or the level of control that was effected, for two out of two years reviewed (2017-2018). Interview on 03/28/2019 at 2:30 PM with the Head of Auxiliary Services confirmed that the QA checklist did not effectively identify and correct the quality control problems in the laboratory for two out of two years (2017-2018).