

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1100637	(X3) Date Survey Completed 04/09/2018
Name of Provider or Supplier Athens Spine Center Pc	Street Address, City, State 830 King Avenue, Athens, GA	
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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) Validation survey was completed on April 09, 2018. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on document review and an interview with the General Supervisor (TP #1 CMS 209), it was determined that the laboratory did not document corrective action taken when Quality Control (QC) on Oxycodone 300 was not in acceptable range on the Siemens Viva-E Analyzer. Findings include: 1.) A review of Quality Control (QC) records revealed that on 7/24/17 and 7/25/17, Oxy 300 control levels were not in acceptable ranges. 2.) An interview with the General Supervisor (TP # 1 (CMS 209) on April 9, 2017 at approximately 12:30 pm in the Conference review room confirmed that no documentation or corrective action was taken on out of range (QC) on 7/24/17 and 7/25/17.</p>