

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2091560	(X3) Date Survey Completed 05/11/2023
Name of Provider or Supplier Neurological Spine And Pain, Llc	Street Address, City, State 8880 Abercon Street, Savannah, 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 recertification survey was performed on May 11, 2023. The facility was found to be NOT in compliance with all applicable CLIA requirements for specialties /subspecialties for 42 CFR.
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 review of the American Proficiency Institute(API) and College of American Pathologist (CAP) Proficiency Testing (PT) providers, for the years 2021 and 2022, for the analyte Ethanol Sulfate and pH, and staff interview, the laboratory failed to verify the accuracy of the pH, and Ethanol Sulfate at least twice annually. Findings: 1. Review of the CAP PT documents for the analyte Ethanol Sulfate, the laboratory was unsuccessful and obtained the following scores: 2021 event A 0% - not submitted by the deadline event B 67% 2022 event A 0% - not submitted by the deadline event B 100% 2. Review of the API PT documents for the analyte pH, the laboratory was unsuccessful and obtained the following scores: 2021 1st event 100% 2021 2nd event 67% 2022 1st event 67% 2022 2nd event 67% 3. Interview with staff #4 and #5 (CMS 209 Personnel Report) on May 11, 2023 at approximately 12 pm, in the meeting area, confirmed the aforementioned statements.</p>
D6017	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently</p>

and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:

Based on review of the College of American Pathologist (CAP) Proficiency Testing (PT) provider, for the years 2021 and 2022, for the analyte Ethanol Sulfate, and confirmed by staff interview, the Laboratory Director (LD) failed to verify that PT results were submitted within the timeframe established by the PT provider. Findings:

1. Review of the CAP PT documents for the analyte Ethanol Sulfate, the laboratory failed to submit the results for the following events and received a score of 0% for failure to participate: 2021 event A 0% - not submitted by the deadline 2022 event A 0% - not submitted by the deadline
2. Interview with staff #4 and #5 (CMS form 209 Testing Personnel List) on May 11, 2023 at approximately 12 pm in the meeting area confirmed the aforementioned statements above.