

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2074675	(X3) Date Survey Completed 03/04/2025
Name of Provider or Supplier Neuromuscular Spine And Joint Center	Street Address, City, State 6720 Grelot Road, Suite A, Mobile, AL	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on reviews of the 2023-2025 Room Temperature (RT) and Humidity logs, the policy and procedure manual, the patient test log, and interviews with the Laboratory Director (LD)/Technical Consultant (TC) and the Practice Manager (PM), the laboratory failed to monitor and document the RT and Humidity for 5 of the 31 days in July 2023. The findings include: 1) A review of the RT and Humidity logs revealed the laboratory failed to monitor and document the RT and Humidity on July 24, 2023, through July 28, 2023. 2) A review of the Procedure for Operating the AU480 Analyzer System ID 47467682 page 1 revealed, 2. Operation: Start Conditions 2.4 Measure and record... 2.4.1 RT between 18 degrees Celsius... 2.4.2 Relative Humidity between 20-80 percent RH ... 3) A review of the July 2023 patient test logs revealed 53 patients were performed during this period when RT and Humidity were not monitored and documented. 4) The LD/TC and the PM confirmed the above findings during the exit conference on 03-04-2025 at 11:45 AM.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p>

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on reviews of the Chemistry maintenance logs, and the policy and procedure manual, and interviews with Laboratory Director (LD)/Technical Consultant (TC) and the Practice Manager (PM), the laboratory failed to document the quarterly and every 6-month maintenance. The surveyor noted no documentation of 12 of the 12 quarterly maintenances from 2023-2025. The surveyor also noted that three of the four every 6-month maintenance were not performed and documented from 2023-2025. The findings include: 1. A review of the Chemistry Beckman Coulter (BC) AU-480 maintenance logs revealed no documentation of the quarterly and every 6-month maintenance on the Beckman Coulter (BC) AU-480 Maintenance Log. 2) A review of the policy and procedure manual under Procedure for Operating the AU480 Analyzer System ID 47467682 page 1-2 revealed, 3. Operation: Maintenance 3.5 Quarterly Maintenance 3.5.1 Clean Air.... 3.5.2 Inspect... 3.6 Every 6-month maintenance 3.6.1 Clean the cuvette... 3. The LD/TC and PM confirmed the above findings during the exit conference on 03-04-2025 at 11:45 AM.