

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D2074675	<b>(X3) Date Survey Completed</b>  02/27/2019
<b>Name of Provider or Supplier</b>  Neuromuscular Spine And Joint Center	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Procedure Manual and an interview with the Technical Consultant, the surveyor determined the laboratory failed to ensure the Quality Control (QC) procedure specified the type(s) and number of controls to be used, the frequency of QC testing, and the criteria for acceptable control results. The findings include: 1. A review of the laboratory policy and procedure manual revealed a generic Quality Control procedure that included definitions and the reasons for QC. However, the procedure failed to specify the type(s) and number of controls to be used, the required frequency of QC testing, and the criteria for acceptable control results. 2.</p>

	<p>During a review of the manual on 2/27/2019 at 12:15 PM, the Technical Consultant confirmed the above noted findings. .</p>
<p><b>D5407</b></p>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Beckman Coulter AU480 Operator's Manual and an interview with the Technical Consultant, the laboratory failed to ensure the Laboratory Director signed, dated and approved the manual for use by the testing personnel. The findings include: 1. A review of the Beckman Coulter AU480 Operator's Manual revealed no signature and date of the current Laboratory Director to indicate review and approval of the manual for use by the testing personnel. 2. During a review of the manual on 2/27/2019 at 12:15 PM, the Technical Consultant confirmed the above noted findings. .</p>
<p><b>D5413</b></p>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(b)</p> <p>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: (1) Water quality. (2) Temperature. (3) Humidity. (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 a review of the 2018-2019 environmental logs, a review of environmental requirements for the Beckman Coulter AU480 Chemistry analyzer and an interview with the Technical Consultant and the Testing Personnel, the surveyor determined the laboratory failed to monitor and document humidity as per manufacturer's instructions for six months. The findings include: 1. A review of the User's Manual for the Beckman Coulter AU480 Chemistry analyzer on page 2-15 revealed the following requirements, "...Temperature and Humidity Conditions When in Use" ... "The humidity is between 20% RH [Relative Humidity] and 80% RH with no condensation...". 2. A review of the September 2018 thru February 2019 laboratory environmental records revealed no documentation of humidity. 3. During a review of the user's manual on 2/27/2019 at 11:55 AM, the Technical Consultant and the Testing Personnel confirmed the room humidity had not been monitored; the Consultant further stated he was not aware of the required environmental parameters specified by the manufacturer. Thus, the above noted findings were confirmed. .</p>
<p><b>D5421</b></p>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it</p>

can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
Based on a review of the installation and validation records for the Beckman Coulter AU480 Chemistry analyzer (used for qualitative drug screen testing and quantitative urine creatinine), and an interview with the Technical Consultant, the surveyor determined the laboratory failed to verify the manufacturer's performance specifications for precision and accuracy before patient testing began. The laboratory further failed to ensure the Laboratory Director reviewed and approved the installation procedures (as indicated by his signature and date) before testing patient samples and reporting results. The findings include: 1. A review of the installation and validation records for the Beckman Coulter AU480 Chemistry analyzer the following: A) Verification of precision for Urine Creatinine failed to pass due to insufficient data (only two points on the graph). B) There was no documentation of studies proving the verification of accuracy for the qualitative urine drug analytes: Amphetamines, Benzodiazepine, Cocaine, Methadone, Opiates, Oxycodone, or Cannabanoids [THC]). C) There was no documentation of review and approval by the Laboratory Director (as indicated by a signature and date) on the initial verification procedures performed on 6/27 and 6/28/2018. 2. Patient testing on the AU480 analyzer began on 9/6/2018. 3. During an interview and review of these records on 2/27/2019 at 12:20 PM, the Technical Consultant confirmed the above noted findings. .

**D5447**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(3)(i)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on reviews of the quality control records for the for the Beckman Coulter AU480 Chemistry analyzer and an interview with the Technical Consultant and the Testing Personnel, the surveyor determined the laboratory failed to ensure two levels of Urine Creatinine quality control (QC) were performed each day of patient testing for six months. The findings include: 1. A review of the QC records for Urine Creatinine on the Beckman Coulter AU480 Chemistry analyzer revealed only one level of QC was performed each day of patient testing from September 2018 thru February 2019. 2. During a review of the QC records on 2/27/2019 at 12:40 PM, the Technical Consultant and the Testing Personnel confirmed only one level of QC for Urine Creatinine has been run since patient testing began on 9/6/2018. .

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification,

either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on a review of patient results reports and an interview with the Technical Consultant and the Testing Personnel, the laboratory failed to ensure the name and address of the laboratory performing the testing was included on the reports. The findings include: 1. On 2/27/2019 at 1:05 PM, the Technical Consultant and the Testing Personnel were asked about the post-analytical process in the facility. Upon the surveyor's request, the Technical Consultant provided a Final Report of a patient's Urine Drug Screen results. 2. A review of the Laboratory Report revealed the laboratory name, address, phone number, fax number and CLIA number did not belong to this facility (Neuromuscular Spine and Joint Center). A second patient report revealed the same error. 3. As the interview continued on 2/27/2019 at 1:15 PM, the surveyor reviewed the report with the Technical Consultant and the Testing Personnel who confirmed their laboratory had performed the urine drug screen testing, however the information on the report was for the reference laboratory in Birmingham that performed the confirmatory drug testing. Thus the above noted findings were confirmed. SURVEYOR ID #32558 Licensure and Certification Surveyor