

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D2157906	(X3) Date Survey Completed 08/23/2021
Name of Provider or Supplier Musc Pathology Outreach Services	Street Address, City, State 173 Ashley Avenue, Charleston, SC	
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
D5403	<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: During an onsite initial survey on 08/23/2021, based on procedure manual review and confirmation by testing personnel, the laboratory failed to establish and maintain a written policy on performing quality control and corrective actions to take when control results fail to meet laboratory criteria for acceptability for histopathology. Findings include: 1. Review of the laboratory procedure manual on 08/23/2021 revealed that there was no quality control policy or corrective actions to take when control results fail to meet laboratory criteria for acceptability for histopathology. 2. Testing personnel confirmed during an onsite interview on 08/23/2021 at 1:50 pm that</p>

there were no written policies on performing quality controls and corrective actions to take when control results fail to meet laboratory criteria for acceptability.