

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 08D1086909	<b>(X3) Date Survey Completed</b> 01/28/2019
<b>Name of Provider or Supplier</b> Cadia Rehabilitation Pike Creek	<b>Street Address, City, State</b> 3540 Three Little Bakers Blvd, Wilmington, DE	
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>D5401</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of the documents provided and interview with testing personnel it was determined that the procedure manual was incomplete. Findings include; 1. Review of the document provided to the surveyor did not include a procedure for how Proficiency Testing would be performed. 2. Interview with testing personnel 1 confirmed that while PT testing was being performed as prescribed by CLIA there was not a procedure describing this.</p>
<b>D6031</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(13)</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 and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;</p> <p>This STANDARD is not met as evidenced by: Based on review of the documents provided and interview with testing personnel 1 it was determined that the procedure manual was not available to all personnel. Findings</p>

include; 1. Review of the document provided proved to be incomplete. 2. Interview with testing personnel 1 confirmed that the procedure manual was maintained on line and not available to all testing personnel. A hard copy signed and dated was later provided.