

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D0970090	<b>(X3) Date Survey Completed</b>  12/07/2018
<b>Name of Provider or Supplier</b>  Pulmonologists Pc	<b>Street Address, City, State</b>  16220 Frederick Road #213, Gaithersburg, MD	
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 review of the procedure manual and interview with the testing person, the laboratory did not have written policies and procedures for entering patient test results into the electronic medial records (EMR). Findings: 1. According to the testing person since 2017 the laboratory results are scanned into the EMR once all the test information is recorded on the worksheet/final report. 2. The laboratory's procedure manual did not have written policies and procedures for maintaining post analytical</p>

paperwork and documenting the results into the EMR system. 3. During there survey on 12/07/18 at 11:00 AM the testing personnel confirmed that the laboratory did not have written post-analytical instructions for entering patient test results into the EMR.