

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0688433	(X3) Date Survey Completed 03/14/2019
Name of Provider or Supplier Pulmonologists Pc	Street Address, City, State 10605 Concord Street #500, Kensington, MD	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the technical consultant (TC), the laboratory director (LD) did perform annual competency procedures for the TC. Findings: 1. The TC did not have annual competency procedures for performing blood gas analysis. 2. The LD did not perform the required six pieces competency assessment that included direct observation, monitoring test results reporting, review of intermediate test results including quality control, proficiency testing and preventative maintenance, assessment of test performance, and problem solving skills. 3. The last annual competency performed for the TC was completed on 11/7/16 and signed by the LD on 3/1/17 4. TC confirmed that competency procedures were not performed during the years 2017 and 2018.</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test</p>

system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on review of the written procedure manual and interview with the testing person, the laboratory did not perform six month calibration verification procedures on the blood gas analyzer. Findings: 1. Review of the written procedure manual showed procedures for performing calibration verification of the blood gas analyzer. 2. The calibration verification procedures were not performed for the years 2017 and 2018. 3. The testing person stated that he was not aware that calibration verification procedures were needed for the blood gas analyzer.