

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0112380	(X3) Date Survey Completed 04/03/2018
Name of Provider or Supplier Holy Name Pulmonary Associates Pc	Street Address, City, State 200 Grand Ave Suite 102, Englewood, NJ	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to maintain and sign the attestation statements for Blood Gas PT performed with the American Associations of Bioanalysts (AAB) in the 2nd and 3rd quarter of 2017. The TP #1 listed on CMS form 209 confirmed on 4/3/18 at 1:30 pm that attestation records were not maintained.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with</p>

	<p>the Testing Personnel (TP), the laboratory failed to review and evaluate PT results obtained from the American Association of Bioanalysts (AAB) for Blood Gas Testing in the 3rd quarter of 2017. The finding includes: 1. There was no review or evaluation documented when the laboratory received an "*" (out of grading range or incorrect response) for the Partial Pressure of Carbon Dioxide (pCO2) on specimen 3. 2. The TP #1 listed on CMS form 209 confirmed on 4/3/18 at 12:40 pm that the laboratory did not review and evaluate PT results.</p>
<p>D5807</p>	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) and interview with the Testing Personnel (TP), the laboratory failed to include the Normal Reference Intervals (NRI) for Oxygen Saturation (SO2) level tests from 4/5/16 to the date of survey. The TP #1 listed on CMS form 209 confirmed on 4/3/18 at 1:55 pm that the laboratory failed to include the NRI on the FR.</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure the Quality Control (QC) Program for Blood Gas tests performed on the Gem Premier 3500 analyzer was maintained in the calendar years 2016 and 2017. The finding includes: 1. Review of the Linearity Verification (LV) data revealed there was no review to determine if results of the LV were acceptable when performed in February 2017 and July 2016 and 2017. 2. The TP #1 listed on CMS form 209 confirmed on 4/3/18 at 2:00 pm that the LD did not ensure the QC program was maintained.</p>