Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0688433	11/18/2021
Name of Provider or Supplier	**Street Address, City, State**	
Pulmonologists Pc	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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (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. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory staff, the Blood gas (chemistry) laboratory did not ensure testing personnel signed the proficiency test providers attestation statement that proficiency testing samples are tested in the same manner as patient samples. Findings: 1. The proficiency testing company that the laboratory enrolled with for blood gas chemistry testing, sends unknown samples to the laboratory for testing, the test results are then submitted to the provider for performance evaluation. The proficiency test provider sends samples to the laboratory three times a year (three separate events); 2. The proficiency provider's attestation statement was not signed by the testing person and laboratory director for the second event of 2021, the first second and third event of 2020 and the third event of 2019; and 3. This was confirmed during interview with Testing Person #1 the afternoon of the day of survey.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210

	If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on record review and interview with Testing Person #1, the blood gas (chemistry) laboratory failed to review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part (see D5211); failed to follow the manufacturer's test system instructions for calibration verification, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer (see D5437); failed to follow control procedures that monitor the accuracy and precision of the complete analytic process and detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance (See D5441); and failed to perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section (See D5445).
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory staff, the blood gas (chemistry) laboratory did not document that the proficiency test provider's evaluation of the laboratory performance was reviewed by the laboratory director. Findings: 1. The proficiency testing company that the laboratory enrolled with for blood gas chemistry testing, sends unknown samples to the laboratory for testing, the test results are then submitted to the provider for performance evaluation. The proficiency test provider sends samples to the laboratory three times a year (three separate events); 2. The proficiency provider's evaluation of the laboratory's performance was not reviewed by the laboratory director for the first, second and third events of 2020 and was not reviewed for the third event of 2019; and 3. This was confirmed during interview with Testing Person #1 the afternoon of the day of survey
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

	This STANDARD is not met as evidenced by: Based on record review and interview with laboratory staff, the blood gas (chemistry) laboratory did not perform calibration verification for chemistry blood gas testing ever six months as required by the manufacturer. Findings: 1. The manufacturer requires the laboratory to perform calibration verification at least every six months and with every test system update made by the manufacturer, using the calibration verification reagents provided by the manufacturer; 2. From the beginning of 2019 through the day of the onsite survey, the laboratory had documentation for performance of two calibration verifications and not five. The calibrations were performed on March 28, 2019 and May 14, 2021; 3. The laboratory also failed to use the five reagent calibration kit supplied by the manufacturer to perform the two calibration verification procedures; and 4. This was confirmed during interview with Testing Person #1 on the afternoon of the day of survey
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory staff, the blood gas (chemistry) laboratory did not follow quality control procedures to ensure that the evaluation of the laboratory's quality control results was performed using the correct range of acceptable quality control results published by the manufacturer. Findings 1. The manufacturer of the quality control reagents requires the laboratory to identify the expected quality control ranges for the lot number in use by going to a web site, selecting the correct letter from the test kit and use this letter along with the kit lot number to make sure that the acceptable ranges match the lot number of the quality control reagent in use; 2. The laboratory performs external liquid quality control testing using three levels of control (Level 1, Level 2 and Level 3) once each week (instead of daily liquid quality control checks each day of patient testing), under the laboratory's Internal Quality Control Plan; 3. The laboratory did not use the correct acceptable limits (assigned by the manufacturer) for the lot number of quality control reagents in use. It was observed by the surveyor in the afternoon of the day of survey that the lot numbers on the quality control test result printout did not agree with the lot number printed on the manufacturer's acceptable ranges used to evaluate the acceptability of the control results; 4. The laboratory failed to follow the manufacturer's procedures to obtain the correct published quality control ranges to evaluate the quality control and made copies of the previous ranges from expired lot numbers of quality control reagent; 5. On the following weeks of quality control testing the lot number of the liquid external control did not match the lot number

	assigned to the manufacturer's published acceptable ranges and patient testing was performed these weeks: a) On November 5, 2021 all three levels (1,2 and 3) did not match B) On October 1, 2021 level one did not match ac) On October 8, 15, 25, 29, 2021 all three levels (1,2 and 3) did not match d) On April 1, 2021 all three levels (1,2 and 3) did not match e) On January 6, 2021 all three levels (1,2 and 3) did not match bf) On November 11, 2020 all three levels (1,2 and 3) did not match G) On July 28, 2021 all three levels (1,2 and 3) did not match H) On January 20, 2021 level 3 did not match. 7. Testing Person # 1 stated during interview on the day of the onsite survey that the laboratory written procedures were not clear that in the event of a quality control failure, a retrospective review of all patient testing for the previous week must be performed as part of the corrective action, due to the fact that the laboratory performs quality control testing only one time each week; and 8. This was confirmed during interview with Testing Person #1 on the afternoon of the day of survey.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory staff, the blood gas (chemistry) laboratory did not follow quality control procedures to ensure that the laboratory tested liquid external quality control reagents prior to testing and reporting patient results. Findings 1. The laboratory performs external liquid quality control testing one time each week using three levels of control (Level 1, Level 2 and Level 3) under it's Internal Quality Control Plan, instead of testing liquid controls each day of patient testing; 2. The laboratory failed to perform liquid external quality control tests during the following weeks of patient testing; a) From November 5, 2018 to February 28, 2019 no external quality control testing was performed. Two patients were reported on February 5, 2019 and one patient was reported on February 18, 2019. b) During the month of March 2019 no external quality control testing was performed and one patient was reported on each of the following days: March 13, 18, 20 25 and 26, 2019, and two patients were tested and results reported March 27, 2019 c) During the month of February 2021 weekly quality control was not performed. One patient result was reported on each of the following days: February 3, 9, 10 and 24, 2021 d) In March 2021 weekly quality control was tested once March 24, 2021. One patient was tested and results reported on March 18, 2021 e) In April 2021, weekly quality control was tested once April 1, 2021. One patient result was reported on each of the following days: April 12, 15, 19, and 23, 2021 f) In May 2021, weekly quality control was tested once May, 14, 2021. One patient result was reported on each of the following days: May 4, 5 and 7, 2021 g) In June 2021 weekly quality control was tested once June 23, 2021. One patient result was reported on each of the following days: June 1, 8, 10, 16 and 22, 2021 h) Weekly quality control was not performed in August 2021. One

	patient was reported on each of the following days: August 4, 15 and 18, 2021. 3. This was confirmed during interview with Testing Person #1 the afternoon of the day of survey.