Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0924110	(X3) Date Survey Completed 12/06/2018
Name of Provider or Supplier Ahmg Suburban Lung Associates	**Street Address, City, State** 800 Biesterfield Rd, Ste 510, Elk Grove Village, IL	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on the surveyor's review of the proficiency testing (PT) documents, test logs, and an interview with the testing personnel (TP), the laboratory failed to test PT samples with the laboratory's regular patient workload, affecting 6 out 6 PT events. Findings: 1. The laboratory is enrolled in a PT program for the testing of the following Blood Gas analytes: Oxygen (O2); Carbon Dioxide (CO2); and ph. 2. The PT records show that the laboratory participated in 6 out of 6 PT events during the years of 2017 and 2018. 3. The patient test log showed that the PT samples for 0 out of 6 PT events, were not recorded in the laboratory's test log along with the patients. 4. On a Recertification survey conducted on 12/06/2018 at 1:30 PM, the TP confirmed the above findings.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on the surveyor's review of the Laboratory Personnel Report (CMS 209), the laboratory's manuals, records, and an interview with the testing personnel (TP), the

	laboratory failed to establish written policies and procedures that meet the personnel requirements in subpart M to assess employees performing Routine Chemistry testing, affecting 6 out of 6 TP. Findings: 1. The CMS 209 lists 6 TP performing Blood Gas analysis in the laboratory. 2. The laboratory's policy and competency procedure does not include the following required competency evaluation processes: a). If applicable, review of intermediate test results or worksheets, quality control records, and preventive maintenance records; and b). Direct observation of performance of instrument maintenance and function checks. 3. The employees' files showed that 6 out of 6 TP were evaluated using the competency procedure that lack the assessment processes listed in findings #2. 4. On a Recertification survey conducted on 12/06 /2018 at 1:30 PM, the TP confirmed the above findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the surveyor's review of the CLIA application for certification (CMS 116), the laboratory's manual, records, and an interview with the testing personnel (TP); the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283 that provides equivalent quality testing for tests performed in the subspecialty of Routine Chemistry, affecting 420 patients' tests. Findings: 1. The laboratory failed to follow its written Individual Quality Control Plan (IQCP) for the Blood Gas analysis performed in the laboratory. See D5401. 2. The laboratory failed to perform and document calibration verification procedures. See D5439.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on the surveyor's review of the CLIA application for certification (CMS 116), the laboratory's manual, records, and an interview with the testing personnel (TP); the laboratory failed to follow written procedures for all tests, assays, and examinations performed by the laboratory, affecting 420 patients. Findings: 1. The laboratory's procedures manual includes an Individual Quality Control Plan (IQCP) for it's Blood Gas analysis testing. The quality control plan (QCP) in this procedure states the following: "Run level 1 and level 3 ISTAT controls on the 1st and 15th (approx.) testing day of every month." 2. The laboratory's I-STAT System QC log: Equivalency Testing" sheets reveal that the laboratory ran the level 1 and level 3 ISTAT controls on the following dates: 2017: 01/19; 02/20; 03/22; 04/19; 05/19; 06/22; 08/22; 09/27;

	10/11; 11/17; and 12/21. 2018: 01/18; 02/21; 05/10; 05/16; 05/22; 06/21; 07/11; 08 /21; 09/27; 10/31; and 12/05. No other documentation was provided as evidence that the laboratory performed quality control testing at least twice a month as instructed in the laboratory's QCP. 3. The CMS 116 signed by the LD states that 420 tests were performed and reported for Blood Gas analysis from January of 2017 through December of 2018. 4. On a Recertification survey conducted on 12/06/2018 at 2:00 PM, the TP confirmed the above findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) 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 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 the surveyor's review of the manufacturer's instruction, manual, records, and an interview with the testing personnel (TP), the laboratory failed to perform and document calibration verification procedures by- * Not following the manufacturer's calibration verification instructions; and by * Not performing the calibration verifications at least once every 6 months; affecting 420 patients' tests. Findings: 1. The manufacturer's instructions for the ISTAT test system used to perform Blood Gas analysis states the following in its technical Bulletin: "Calibration Verification is a procedure intended to verify the accuracy of results over the entire measurement range of a test. The performance of this procedure at defined intervals may be required by regulatory accreditation bodies." 2. The laboratory's manual does not include in it's procedures the instructions to perform calibration verification procedures as instructed by the manufacturer in order to fulfill the 'regulatory bodies' requirements. 3. The quality control records reviewed showed no documented evidence that the laboratory perform calibration verification on it's ISTAT instrument during the years of 2017 through 2018. 4. The CMS 116 signed by the LD states that 420 tests were performed and reported for Blood Gas analysis from January of 2017 through December of 2018. 5. On a Recertification survey conducted on 12/06/2018 at 2:00 PM, the TP confirmed the above findings.
D5807	TEST REPORT

	CFR(s): 493.1291(d) 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. This STANDARD is not met as evidenced by: Based on the surveyor's review of the patients' test results, final report, laboratory's volume worksheet, and an interview with the testing personnel (TP); the laboratory failed to ensure reference ranges or normal values are included in the final test report, affecting 140 patients' final reports. Findings: 1. The "final report" does not to include the "reference intervals" or "normal" values for the Blood Gas analytes: Oxygen (O2); Carbon Dioxide (CO2); and ph tests the laboratory reports. 2. The laboratory reports on the "Laboratory Non-waived CLIA Test Volume Worksheet" that the laboratory has performed Blood Gas analysis for 140 patients. 3. On a Recertification survey conducted on 12/06/2018 at 1:45 PM, the TP confirmed the above findings.