

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D1005462	(X3) Date Survey Completed 03/11/2026
Name of Provider or Supplier Alveoli Corporation DbA Lungs At Work	Street Address, City, State 5000 Waterdam Plaza Drive, Suite 180, McMurray, PA	
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
D0000	A recertification survey was conducted by the Pennsylvania State Agency at Alveoli Corporation dba Lungs at Work on 03/11/2026. The laboratory was found out of compliance with the following condition: 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant.
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records and interview with the Patient Care and Office Coordinator (PCOC), the Laboratory Director (LD)/designee failed to sign 2 of 4 API PT attestation statements for blood gas testing performed from 07/18/2024 to 03/11/2026. Findings include: 1. The API PT attestation form stated, "The undersigned certify that, as closely as possible, these proficiency testing samples were tested in the same manner as patient specimens." 2. On the day of the survey, 03/11/2026 at 10:30 am, the laboratory failed to provide attestation statements signed by the LD/designee for the following 2 of 4 API PT events performed from 07/18/2024 to 03/11/2026: - 2025 Chemistry - Core - 2nd Event - 2025 Chemistry - Core - 3rd Event 3. The PCOC confirmed the findings above on 03/11/2026 at 11:36 am.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for</p>

proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on record review, lack of documentation, and interview with the Patient Care and Office Coordinator (PCOC), the laboratory failed to monitor and document relative humidity for 601 of 601 days to ensure operating conditions were met for reliable test system operation and test result reporting of blood gas testing performed from 07/18/2024 to 03/11/2026. Findings Include: 1. The GEM Premier 5000 Operations Manual stated, "Ambient Environmental Requirements: Relative Humidity Limits 15 to 85 % RH (non-condensing)." 2. On the day of survey, 03/11/2026 at 10:39 am, review of the laboratory's temperature and humidity control logs revealed the laboratory failed to monitor and document relative humidity when blood gas testing was performed on the GEM Premier 5000 analyzer for 601 of 601 days from 07/18/2024 to 03/11/2026. 3. The laboratory performed 208 blood gas tests in 2025 (CMS 116, estimated annual volume, dated 03/10/2026). 4. The PCOC confirmed the findings above on 03/11/2026 at 11:36 am.

D5435

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(2)

(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
Based on record review, lack of documentation, and interview with the Patient Care and Office Coordinator (PCOC), the laboratory failed to establish and maintain a maintenance/function check policy for 2 of 2 thermometers used to ensure acceptable storage and operating temperatures were met in the laboratory for blood gas testing performed from 07/18/2024 to 03/11/2026. Findings include: 1. On the day of survey, 03/11/2026 at 10:52 am, the surveyor observed the following thermometers used in the laboratory to monitor acceptable storage and operating temperatures of equipment, reagents, and supplies: - Taylor refrigerator thermometer. - Ambient Weather room temperature monitor. 2. Review of laboratory procedures revealed the laboratory failed to establish and maintain a maintenance/function check policy for 2 of 2 thermometers used to ensure acceptable storage and operating temperatures were met in the laboratory for blood gas testing performed from 07/18/2024 to 03/11/2026. 3. The PCOC confirmed the findings above on 03/11/2026 at 11:36 am.

D6033

TECHNICAL CONSULTANT-MODERATE COMPLEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on record review and interview with the Patient Care and Office Coordinator (PCOC), the laboratory failed to ensure 1 of 1 testing personnel (TP) (CMS 209, TP #1, dated 03/10/2026) that performed the duties of a technical consultant met the minimum education requirements listed under 493.1411 to provide technical oversight for moderate complexity blood gas analysis in 2024 and 2025. Refer to D6035

D6035

TECHNICAL CONSULTANT QUALIFICATIONS

CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; AND (b)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

This STANDARD is not met as evidenced by:

Based on record review and interview with the Patient Care and Office Coordinator (PCOC), the laboratory failed to ensure that 1 of 1 Testing Personnel (TP) who performed the responsibilities of a technical consultant (TC) met the minimum education requirements listed under 493.1411 to provide technical oversight for moderate complexity blood gas analysis from 07/18/2024 to 03/11/2026. Findings include: 1. On the day of the survey, 03/16/2026 at 09:20 am, review of personnel credentials revealed TP #1 obtained an Associate Degree in Respiratory Therapy. 2. Further review of the laboratory's competency assessment (CA) and Quality Assurance (QA) records revealed the laboratory failed to ensure that 1 of 1 TP (CMS 209, TP #1, dated 03/10/2026) met the minimum educational requirements to perform the following duties of a TC listed under C.F.R. 493.1413 from 07/18/2024 to 03/11/2026: - Direct observations and sign-off of CA records for TP #1 and TP #2 in 2024 and 2025 - QA monthly review in 2024 and 2025 3. The Form CMS-209, signed by the laboratory director (LD) on 3/10/2026, did not list TP # 1 as a TC. 4. The laboratory performed 208 blood gas tests in 2025 (CMS 116, estimated annual volume, dated 03/10/2026). 5. The PCOC confirmed the findings above on 03/11/2026 at 11:36 am.