

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D1005462	(X3) Date Survey Completed 12/06/2022
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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Gem 5000 Blood Gas analyzer validation records and interview with Testing Personnel (TP)#1, the laboratory failed to establish criteria for acceptable performance specifications for the Gem 5000 Blood Gas analyzer validation used for routine chemistry specimens from December 17, 2021 to December 06, 2022. Findings Include: 1. On the day of the survey, 12/06/2022 at 12:35pm, review of the Gem 5000 Blood Gas analyzer validation records revealed that the validation performed on 12/17/2021 did not include criteria for acceptable precision, accuracy, and reportable range. 2. TP#1 confirmed the findings above on 12/06/2022 around 01:25pm.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p>

This STANDARD is not met as evidenced by:
Based on review of the laboratory competency assessment records and interview with Testing Personnel (TP)#1, the Technical Consultant (TC) failed to evaluate the competency assessment of 2 of 2 Testing Personnel (TP) who performed Blood Gas examinations in 2021 and 2022. Findings include: 1. On the day of survey 12/06/2022 at 11:51 am, the laboratory could not provide competency assessment records performed by the TC for 2 of 2 TP (CMS 209 personnel #2 and#3) who performed Blood Gases in 2021 and 2022. 2. TP#1 confirmed the finding above on 12/06/2022 at 01:25 pm.