

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D2195629	(X3) Date Survey Completed 12/04/2023
Name of Provider or Supplier Aer Medical Llc	Street Address, City, State 1200 Airport Heights Bld E Suite 200, Anchorage, AK	
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on a surveyor review of proficiency testing (PT) records, and an interview with the Technical Consultant, the laboratory failed to enroll in an approved proficiency testing program for Microalbumin/Creatinine for 2023. 1. A request was made to review proficiency testing records for Microalbumin/Creatinine and documentation could not be provided. 2. An interview with the Technical Consultant on 12/04/2023 at 11:30 AM, confirmed the laboratory did not subscribe to Proficiency Testing for Microalbumin/Creatinine for 2023. 3. The laboratory reports performing forty two (42) Microalbumin/Creatinines annually.</p>
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)</p>

(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.

This STANDARD is not met as evidenced by:

Based on a lack of documentation and an interview with the Technical Consultant (TC), the laboratory failed to verify the accuracy, precision, reportable range, and reference range for the Siemens DCA Vantage analyzer prior to reporting patient Microalbumin/Creatinine test results beginning January 12, 2023. Findings include: 1. A request was made to review verification records for the Siemens DCA Vantage and documentation could not be provided. 2. An interview with the Technical Consultant on 12/04/2023 at 11:30 AM, confirmed the laboratory did not have documentation or evidence of accuracy, precision, reportable range, or reference range verification. 3. The laboratory reports performing forty two (42) Microalbumin/Creatinines annually.