Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	48D2122646	09/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Aeromd	8203 Lindberg Bay, St Thomas, VI	

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	An announced CLIA recertification survey was conducted at AeroMD on September 22, 2021 by the Centers for Medicare and Medicaid Services (CMS) New York branch federal surveyor. The laboratory was surveyed under 42 CFR part 493 CLIA requirements: Specific deficiencies cited are as follows:
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on Proficiency testing (PT)records, lack of documentation and interview the laboratory failed document proficiency testing evaluation and review for unsatisfactory scores and the corrective action taken by the testing personnel. Findings include: On 09/22/2021 at approximately 11:00 am a review of the proficiency testing results for Critical Care Aqueous Blood Gas AQI-C- 2020 revealed the following Regulated Analyte: Blood Gas, PO2 Proficiency Event: 2020 #3 Event Interpretation: Unsatisfactory Score 3/5 = 60% The surveyor requested documentation for the policy for evaluating and reviewing unsatisfactory results the laboratory failed to provide evidence of corrective action. During an interview at approximately 11:23AM, the technical consultant stated "Normally, we just send an email to correct errors and issues to the laboratory director". During the exit interview on 09/22/2021 at approximately 1:50 PM the laboratory director confirmed the above findings.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test

	results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: A. Based on review of calibration records and interview the laboratory failed to document corrective action performed for the i-STAT CART (EXC EC8+) when the calibration verification was not acceptable according to Blood Gas Calibration Verification/ Linearity Evaluation provided by College of American Pathologist (CAP). Findings Include On 09/22/2021, at approximately 11:10 AM, a review of the LN13- A 2021 Blood Gas Calibration Verification/ Linearity Evaluation records revealed the laboratory received not acceptable result for the following analytes: PCO2 mm Hg: Different Potassium mm Hg: Different Sodium: Non- Linear The Blood Gas Calibration Verification/ Linearity Evaluation kit states "For Results of Different, see the Calibration Verification Troubleshoot Guide and Investigate Checklist" The surveyor requested the investigation /corrective action documents, the technical consultant (TC) stated "Normally we just send an email to the Laboratory Director (LD). Unfortunately, I don't have an email to the LD about the failed linearity. B. Based on a review of Quality Control (QC) records, i-STAT procedure manual and the interview with the Technical Consultant (TC) the laboratory failed to document corrective action performed for QC failure on the i-STAT Blood Gas instrument. Findings include At approximately 12:15 PM on 09/22/2021, a review of i- STAT QC records from 01/01/2021 - 09/22/2021 revealed seven QC failures for the EQC control type on the Simulator. Date/ Serial Number/Result a. 01-18-2021/ 353824/ Fail b. 01-22-2021/353824/ Fail c. 04-01-2021/369993/Fail d. 06-06-2021 /353824/ Fail e. 07-28-2021/353824/ Fail f. 08-04-2021/353824/ Fail g. 08-22-2021 /369993/ Fail A review of the procedure manual for the i-STAT system revealed, Remedial Action Section, stating "Record the QC failure in the i-STAT QC Action Log along with the action taken". The surveyor requested the QC Action Log, the TC stated "That is not something the system captures so unfortunately I do not have one to provide for you" During the exit interview on 09/22/2021 at approximately 1:50 PM the laboratory director confirmed the above findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on lack of documentation, record review and interview with the technical consultant the laboratory failed to provide a policy and procedure for analytic system quality assessment. Findings include: On 09/22/2021 at approximately 1:35 PM the surveyor requested the laboratory Quality Assessment (QA) procedures for the following: - Analytic Systems o Due to lack of documented corrective actions for unsuccessful calibration verification, linearity studies, Quality Controls (QC),

	proficiency testing scores. The technical consultant stated "No, I don't think we have that." During the exit interview on 09/22/2021 at approximately 1:50 PM the laboratory director confirmed the above findings.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a lack of documentation and interview the laboratory director failed to ensure that a quality assessment program is established and maintained. Findings include: On 09/22/2021 the surveyor requested the laboratory Quality Assessment (QA) procedures for the following: - General Laboratory Systems: - Lack of documented corrective actions Proficiency Testing Performance - Analytic Systems - Lack of documented corrective actions for unsuccessful calibration verification, linearity studies, Quality Controls (QC), proficiency testing scores. The technical consultant stated "No, I don't think we have that." During the exit interview on 09/22 /2021 at approximately 1:50 PM the laboratory director confirmed the above findings.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on lack of documentation and interview the technical consultant failed to resolve technical problems and ensuring that remedial actions are taken when calibration verification and linearity studies for the i- STAT test system deviated from the laboratory acceptable ranges. Findings include: Refer to D5783 subsection A and B.