Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	48D2122646	06/15/2023
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	The Centers for Medicare & Medicaid Services (CMS) federal surveyor conducted an announced CLIA recertification survey at AeroMD on June 15, 2023. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The findings were reviewed with the Laboratory Director and Technical Consultant at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulations: 493.1210; D5016: Routine Chemistry 493.1215; D5024: Hematology
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on record review and interview with the Technical Consultant (TC), the laboratory failed to ensure the requirements were met for the subspecialty of Routine Chemistry. Findings include: 1. The laboratory failed to perform two levels of control materials each day of patient chemistry testing using the Chem 8+ cartridge and CG4+ cartridge with the iSTAT analyzer for 16 of 16 days of patient testing. Refer to D5447.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299.

	This CONDITION is not met as evidenced by: Based on record review and interview with the Technical Consultant (TC), the laboratory failed to ensure the requirements were met for the subspecialty of Hematology. Findings include: 1. The laboratory failed to perform two levels of control materials each day of patient hematology testing using the Chem 8+ cartridge with the iSTAT analyzer for 16 of 16 days of patient testing. Refer to D5447
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with the Technical Consultant (TC), the laboratory failed to perform two levels of control materials each day of patient testing for 16 of 16 days of patient testing. Findings include: 1. Interview with the TC on 06 /15/2023 at 10:30 AM confirmed the laboratory performed chemistry, hematology, and blood gas testing using the iSTAT system: a. Chem 8+ cartridge analytes - Sodium, Potassium, Chloride, TCO2, Ionized Calcium, Glucose, Urea Nitrogen, Creatinine, Hematocrit b. CG4+ cartridge analytes - pH, PCO2, PO2, Lactate 2. Interview with the TC on 05/15/2023 at 01:00 PM confirmed an Individualized Quality Control Plan (IQCP) was not available during the survey for the iSTAT test system. 3. Review of quality control (QC) and patient testing records from 01/05/2023 through 03/17/2023 revealed two levels of QC material were not performed each day of a patient testing for 16 of 16 days of patient testing. a. Chem 8+ Cartridge Patient 2300021 - test performed 01/09/2023 at 03:06 AM Patient 2200040 - test performed 01/11/2023 at 01:58 PM Patient 2200050 - test performed 01/13/2023 at 04:27 AM Patient 2200055 - test performed 01/15/2023 at 03:23 AM Patient 2300059 - test performed 01/16/2023 at 05:50 AM Patient 2300064 - test performed 01/18/2023 at 04:19 AM Patient 2300127 - test performed 02/03/2023 at 09:43 AM Patient 2300120 - test performed 02/05/2023 at 03:33 PM Patient 2300168 - test performed 02/14/2023 at 10:44 AM Patient 2300170 - test performed 02/15/2023 at 10:19 AM Patient 2300192 - test performed 02/20/2023 at 06:11 PM Patient 2300238 - test performed 03 /07/2023 at 01:17 PM Patient 2300248 - test performed 03/08/2023 at 01:44 PM Patient 2300255 - test performed 03/10/2023 at 10:53 AM Patient 2300259 - test performed 03/12/2023 at 08:20 AM Patient 2300289 - test performed 03/17/2023 at 07:34 PM b. CG4+ Cartridge Patient 2300014 - test performed 01/05/2023 at 09:20 AM Patient 2300021 - test performed 01/09/2023 at 03:02 AM Patient 2200040 - test performed 01/11/2023 at 01:54 PM Patient 2200050 - test performed 01/13/2023 at 04: 32 AM Patient 2200055 - test performed 01/15/2023 at 03:27 AM Patient 2300059 - test performed 01/16/2023 at 05:54 AM Patient 2300064 - test performed 01/18/2023 at 04:15 AM Patient 2300127 - test performed 02/03/2023 at 09:43 AM Patient 2300120 - test performed 02/05/2023 at 03:20 PM Patient 2300168 - test performed 02 /14/2023 at 10:49 AM Patient 2300170 - test performed 02/15/2023 at 10:15 AM Patient 2300192 - test performed 02/20/2023 at 06:07 PM Patient 2300238 - test performed 03/07/2023 at 01:13 PM Patient 2300289 - test performed 03/17/2023 at 07:

	31 PM Patient 2300259 - test performed 03/12/2023 at 08:20 AM Patient 2300289 - test performed 03/17/2023 at 07:34 PM 4. Interview with TC on 06/15/2023 at 02:00 PM confirmed the findings as indicated above.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and interview with the Technical Consultant (TC), the laboratory failed to include the address of the laboratory location for one of one patient report. Findings include: 1. Interview with the TC on 06/15/2023 at 10:30 AM confirmed the laboratory performed chemistry, hematology, and blood gas testing using the iSTAT system: a. Chem 8+ cartridge - Sodium, Potassium, Chloride, TCO2, Ionized Calcium, Glucose, Urea Nitrogen, Creatinine, Hematocrit b. CG4+ cartridge - pH, PCO2, PO2, Lactate 2. Record review on 06/15/2023 of a patient report (patient 23-00414 tested on 04/16/2023) revealed that for one of one report, the address of the laboratory was not included on the patient report. 3. Interview with the TC on 06/15 /2023 at 11:30 AM confirmed the findings as indicated above.