Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	48D2122646	08/27/2025
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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on review of 2024, 2025 i-STAT quality control documentation, Abbott i-STAT manufacturer's package insert, and interview with the technical consultant (TC), the laboratory failed to retain QC for two of seven months. Findings included: 1. Review of 2024, 2025 i-STAT QC documentation showed the laboratory failed to retain QC records and the package inserts with the expected values for November 2024 and April 2025. 2. Interview with the TC on August 25, 2025 at 4:20 PM confirmed the laboratory failed to retain the quality control results and package inserts. 3. The laboratory reports approximately 2400 chem 8 and 200 arterial blood gas patient results annually.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

	This CONDITION is not met as evidenced by: Based on review of procedures, quality control documentation, patient reports, and interviews, the laboratory failed to meet the condition of analytic systems. The laboratory failed to follow their quality control procedure (Refer to D5401); failed to perform QC using the number and frequency established by the laboratory (Refer to D5445); and failed to perform twice yearly instrument comparisons for four of four Abbott i-STAT analyzers (Refer to D5775).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the procedure manual, review of 2025 i-STAT quality control (QC) documentation for four of four i-STAT analyzers, and interview with the technical consultant (TC), the laboratory failed to follow the procedure for one of four months in 2025. Findings included: 1. Review of the procedure titled, ""Lab Quality Control and Quality Assurance Program" showed "Liquid QC is run when lots are changed and new shipments are received and if extensive maintenance is performed on the analyzer or every month." 2. Review of "Procedure for use of Abbott i-STAT Analyser" Section 10 Quality Control showed, "This is performed by laboratory staff: Aqueous assayed control solutions are used to verify the integrity of each batch of cartridges that are issued for use from stock in Biochemistry. Control solution i-STAT control level 1 and i-STAT tricontrol control level 3." 3. Review of level 3 QC for Chem 8 and CG4 cartridges for the i-STAT analyzer serial #445201 showed no level 3 QC performed for April 2025. 4. Interview with the TC on 8/25/2025 at 4:20 PM confirmed the laboratory failed to follow the procedure for QC. 5. The laboratory reports approximately 2400 chem 8 and 200 arterial blood gas patient results annually.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on review of the laboratory's Individualized Quality Control Plan (IQCP), review of three months for 2024 and four months for 2025 of i-STAT quality control (QC) documentation, and interview with the technical consultant (TC), the laboratory failed to perform control procedures using the number and frequency established by

	the laboratory. Findings included: 1. Review of the laboratory's IQCP "Lab Quality Control and Quality Assurance Program" showed "Liquid QC is run when lots are changed and new shipments are received and if extensive maintenance is performed on the analyzer or every month." 2. No QC documentation for February 2024 was available for review per their IQCP. 3. Review of November 2024 showed for the i-STAT analyzer serial #369993, the laboratory failed to perform QC for Chem 8 and CG4 cartridges. 4. Two patients were tested on 11/11/2024 and 11/14/2024 on the i-Stat analyzer serial #369993. 5. Interview with the TC on 8/25/2025 at 4:46 PM confirmed the laboratory failed to perform QC on the i-STAT analyzer #369993 for the month of November 2024. 6. Interview with the TC on 8/25/2025 at 4:50 PM confirmed there was confusion with the staff about frequency of QC and on which i-Stats. The TC confirmed the laboratory failed to perform QC using the number and frequency established by the laboratory. 7. The laboratory reports approximately 2400 chem 8 and 200 arterial blood gas patient results annually.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on review of the laboratory's instrument comparison procedure, review of four of four Abbott i-STAT instrument comparison documentation, and interview with the technical consultant (TC) #1, the laboratory failed to perform comparisons twice a year for 2024. Findings include: 1. Review of the procedure titled "Test Method Validation, Method Comparison" section VI showed, "Comparison Studies are completed on instruments at least twice a year, due to the low volume of patient samples an alternate method is used. Quality Control data may be used. AeroMD participates in the CAP Quality Cross Check Program." 2. No instrument comparison documentation for 2024 was available for review for four of four i-STAT analyzers for chemistry and hematology testing. 3. Interview with the TC #1 on 8/25/2025 at 3: 30 PM confirmed the laboratory failed to perform twice yearly instrument comparisons for four of four Abbott i-STAT analyzers. 4. The laboratory reports approximately 2400 chem 8 and 200 arterial blood gas patient results annually.