Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2307899	01/22/2025
Name of Provider or Supplier	**Street Address, City, State**	
Ams Cardiovascular Asc	507 Prudential Rd, Horsham, 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
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 review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, and interview with Testing Personnel (TP) #1 (CMS 209 personnel #8), the laboratory failed to document the evaluation and verification activities performed for 1 of 1 API Chemistry Core PT testing events in 2024. Findings include: 1. The API PT Performance Evaluation Form states, "Laboratories should review the Performance Summary and Comparative Evaluation thoroughly for failures or ' not graded' analytes." 2. On the day of the survey, 01/22/2025 at 11:00 am, review of API PT records revealed the laboratory director/designee failed to document the evaluation and verification activities performed for the API Chemistry Core PT 3rd Event performed in 2024. 3. TP #1 confirmed the findings above on 12/10 /2024 at 11:22 am.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 lack of documentation and interview with Testing Personnel (TP) #1 (CMS 209 personnel #8), the laboratory failed to verify the performance specifications for hematology and chemistry tests analyzed on 1 of 1 Abott i-STAT prior to reporting patient test results from 10/24/2024 to the date of the survey. 1. On the day of the survey, 01/22/2025 at 10:33 am, the laboratory failed to provide documentation for the verification of performance specifications for precision, accuracy, reportable range, and reference intervals/range for the following analytes tested on 1of 1 Abott i-STAT before reporting patient results from 10/24/2024 to 01/22/2025: - Activated Clotting Time (ACT) - pH - Partial Pressure Carbon dioxide (PCO2) - Partial Pressure of Oxygen (PO2) - Potassium - Sodium - Ionized Calcium (iCa) - Hematocrit (Hct) - Hemoglobin (Hb) - Bicarbonate (HCO3) - Total Carbon Dioxide (TCO2) - Oxygen Saturation (sO2) - Base Excess (BE) 2. The laboratory could not provide a procedure of new instruments, analytes, or methodology. 3. The laboratory performed 150 Chemistry tests and 108 hematology tests in 2024 (CMS 116 annual volume) 4. TP#1 confirmed the findings above on 01/22/2025 at 11:22 am.