Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D2221136	09/16/2026
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Heart & Vein Surgery, Llc	805 E 144th Ave, Suite 200, Thornton, CO	

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	Based on an on-site recertification survey conducted on September 16, 2026, deficiencies were cited for Advanced Heart and Vein Surgery, LLC laboratory loacated in Thornton, Colorado.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a surveyor review of Avoximeter 1000E procedure manual, a surveyor review of Avoximeter 1000E maintenance documents, and an interview with the technical consultant (TC) during the survey, the laboratory failed to perform and document calibration verification procedures at least once every 6 months. The laboratory performs approximately 1000 routine chemistry tests annually. Findings

	include: 1. A surveyor review of Avoximeter 1000E procedure manual revealed the laboratory must run calibration verification controls twice annually. 2. A surveyor review of Avoximeter 1000E maintenance documents revealed the laboratory has not performed calibration verification since the beginning of operation in 2024. 3. An interview with TC on September 16, 2026, at 12:30 PM confirmed that the laboratory has not performed calibration verification since the beginning of operation in 2024.
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 the surveyor review of the laboratory quality control documents and an interview with the technical consultant (TC), the laboratory failed to perform Quality Control (QC) at least once each day patient specimens are tested with Avoximeter 1000E. The laboratory performed approximately 1000 tests annually since the start of the test in 2024. Findings include. 1. A surveyor review of the laboratory quality control documents for Avoximeter 1000E instrument revealed that the laboratory performs three levels of liquid quality control weekly. 2. An interview with the TC, on September 16, 2026, at 12:18 PM confirmed the laboratory performs three levels of liquid quality control weekly for Avoximeter 1000E instrument.