Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0967732	07/14/2026
Name of Provider or Supplier	**Street Address, City, State**	
Apex Cardiology Consultants	501 E Hardy St Ste 200, Inglewood, CA	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policies and procedures, five (5) patient test record from 11/20/2024 to 02/17/2026, lack of the technical consultant (TC) competency documentation, and interview with the TC on July 14,, 2026, as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to perform and document competency assessments for the TC in subpart M. The findings included: 1. The laboratory had performed competency assessments for the testing personnel. However, no documentation for competency assessments for the TC was performed for the years 2024 and 2025. 2. TC confirmed by interview on July 14, 2026, at approximately 12:45 p.m. that the laboratory lacked competency assessments for the years 2024 and 2025 for the TC. 4. According to the testing declaration form (Lab-144) submitted at the time of survey, the laboratory performed and reported approximately 57,000 tests annually including the period when the TC competency assessment was not performed.
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 the lack of laboratory's standard operating procedures, five (5) randomly selected patient test results, and interviews with the technical consultant (TC) and testing personnel (TP); the laboratory failed to have written procedures for all tests, assays, and examinations performed by the laboratory available and followed by laboratory personnel .The findings included: 1. The laboratory lacked written laboratory procedures approved by the laboratory director for all tests, assays, and examinations currently performed in the laboratory. 2. The laboratory did not have written procedures for the test performed in the laboratory; routine chemistry, endocrinology, and hematology. 3. Reliability of the laboratory tests' performance based on a complete written and approved laboratory procedure to follow by testing personnel to ensure compliance with federal CLIA regulations could not be assured during this survey. 4. TC and TP affirmed by an interview on July 14, 2026, at approximately 12:30 p.m. that the laboratory failed to provide LD signed, dated, and approved written laboratory procedures for all the current tests and examinations performed in the laboratory. 5. According to the testing declaration form (CMS-116) submitted at the time of survey, the laboratory processed, tested, and reported approximately a total of 57,000 patient tests annually when the laboratory lacked written and approved standard operating procedures for all tests performed in the laboratory.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory policies, the lack of laboratory written standard operating procedures, and interview with the technical consultant (TC) and testing personnel (TP); the laboratory failed to have written requirements for specimen management, process for documenting failures and noncompliance, appropriate corrective actions, and monitoring for recurrence. Findings included: 1. The laboratory failed to have CLIA compliant written requirements for positive patient identification, patient preparation, specimen collection and labeling, storage,

	preservation, transportation, referral specimen, and criteria for specimen acceptability and rejection. 2. The laboratory performed self-audits consisting of one patient test per month. However, no written policy on how to perform, document, and remedial corrections as appropriate to monitor for quality assurance and compliance was available at the time of the inspection. 3. TC and TP confirmed by interview on July 14, 2026, at approximately 12:30 p.m. findings stated above in 1. and 2. 4. For five (5) out of five (5) patients' records reviewed no written standard operating procedures for all the tests performed and policies for self-audits were found.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the surveyor's direct observation during the laboratory tour, review of the laboratory's policies and procedures, preventive maintenance (PM) documentation, and interviews with the laboratory's technical consultant (TC) and testing personnel (TP); the laboratory failed to establish and follow a policy and procedure in place for preventive maintenance as defined by the manufacturer, with at least the frequency recommended for the laboratory's equipment prior to patient testing. The findings included: 1. The laboratory failed to provide PM documentation for the years 2024, 2025, and 2026 for the room thermometer used daily to monitor room temperature as required for the equipment used for laboratory testing. 2. No corrective action report for preventive maintenance was available for review at the time of the survey. 3. TC and TP affirmed by interviews on July 14, 2026, at approximately 12:45 p.m., that the laboratory missed the PM for the years 2024, 2025, and 2026 for the room temperature thermometer used in the laboratory for patients' testing equipment requirements. 4. According to the testing volume declaration submitted at the time of the survey, the laboratory performed and reported approximately 57,000 tests annually during the time annual equipment PM for the room thermometer was missing.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: The laboratory director is herein cited for deficient practice in ensuring that systems for the preanalytic, analytic, and postanalytic phases of the laboratory were monitored and followed. Findings include: 1. The technical consultant did not receive competency assessments for the years 2024, 2025, and 2026. See D5209 2. The laboratory failed to have a policy and procedure for equipment preventive maintenance including calibration of conventional thermometer to take daily room temperature as required. See D5429.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(13) (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on direct observation, lack of standard policies and procedures, and interviews with the laboratory's technical consultant and testing personnel; it was determined that the laboratory director failed to ensure that a signed, approved, and dated written policies and procedures for all aspects of laboratory test is always available to all personnel responsible for any aspect of the testing process. See D5401 and D5403.