

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0967732	(X3) Date Survey Completed 04/20/2023
Name of Provider or Supplier Apex Cardiology Consultants	Street Address, City, State 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
D3033	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i)</p> <p>In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's test validation records, and interview with the laboratory technical consultant and testing person on April 20, 2023, at 12:30 pm, the laboratory failed to retain the test validation records. The findings include: 1. The laboratory verified routine chemistry tests on the Alpha Wassermann Axcel instrument. The test manufacturer ran the verification tests. The laboratory required to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (A) Accuracy. (B) Precision. (C) Reportable range of test results for the test system. However, the laboratory did not have records for accuracy verification. Verification of accuracy may be accomplished by: Testing reference materials; Comparing results of tests performed by the laboratory against the results of a reference method; or Comparing split sample results with results obtained from another method, which has already been shown to provide accurate results. Therefore, it can be assured that the laboratory verified the tests accuracy. 2. The laboratory technical consultant and testing person on April 20, 2023, at 12:30 pm, affirmed that the records were not in the laboratory. 3. The laboratory's testing declaration form, signed by the laboratory director on 4/5/2023 stated that the laboratory performs approximately 40,000 tests, annually.</p>
D6004	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</p>

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappropriates performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's test validation records, and interview with the laboratory technical consultant and testing person on April 20, 2023, at 12:30 pm, it was determined that the laboratory director failed to direct the overall operation and administration of the laboratory. The findings include: See D3033.