Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0683179	05/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Cardiovascular Diagnostics Pllc	833 Northern Blvd Suite 100, Great Neck, NY	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 a surveyor's review of the laboratory's procedure manual and an interview and confirmed with the technical consultant, the laboratory failed to have a procedure manual that is comprehensive. FINDINGS: The procedure manual did not include: 1) A written procedure describing calibration of the pipettes; 2) Lot to lot verification of new controls; 3) Written hematology calibration procedures to include the frequency; 4) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability; 5) A written procedure describing laboratory's turnaround time from sample collection to processing and to when final results are

	entered into the lab computer system; 6) A written Proficiency testing (PT) policy including timely enrollment, PT testing review of reports received, the corrective action procedure to be followed for ungraded and if any score is less than 100%, and PT record retention.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 the surveyor's review of the laboratory's records and an interview with the technical consultant and the testing person, the laboratory failed to establish and verify the performance specifications for the Coulter AcT 5 Diff hematology analyzer which was installed in May 2018. Patient testing was initiated in April 2019. Findings: 1. On May 13, 2019 at approximately 12:30 PM, the technical consultant confirmed that although there were records indicating that calibration, accuracy and precision were performed at the time of installation in May 2018, there were no records of reference range and reportable range as part of a complete validation of the Coulter AcT 5 Diff analyzer. 2. Approximately 100 patient specimens were tested and reported for hematology when the above analyzer was used for patient testing during the above time frame.