Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0580198	01/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Biomedical, Inc	3098 S Harbor Blvd, Santa Ana, 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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (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 review of the laboratory a records, and interview with the laboratory staff, it was determined that the laboratory failed to perform and document calibration verification (CV) procedures at least twice a year, 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. The findings included: a. The laboratory used Beckman Coulter AU 680 to perform

	routine chemistry and reported electrolytes including sodium, potassium, chloride and CO2. b. The testing procedures for electrolyte tests requires to perform and document CV at least twice annually to verify the reportable range of test. results for the system. c. The laboratory failed to perform and document the CV, at least twice, for electrolytes in the year of 2016-2017. d. The laboratory affirmed (1/12/2018 @13:25) that the laboratory failed to perform CV as required by the CLIA rules and regulations.
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory quality control records, and interview with the laboratory staff, it was. Determined that the laboratory failed to perform control procedures for antimicrobial susceptibility test each day are performed including its zone sizes or minimum inhibitory concentration for control organisms within established limits before reporting patient results. The findings included: a. Interview with the laboratory staff for the antimicrobial susceptibility test, the laboratory performed quality control for antimicrobial susceptibility weekly. b. The laboratory affirmed (1/12/2018 @ 12:25) that the laboratory used IQCP quality control procedures. c. No laboratory documents to support the laboratory had followed IQCP protocol to establish the IQCP quality control procedures. d. The laboratory affirmed (1/12/2017 @ 12:30) that the failed to perform IQCP protocol to establish antimicrobial susceptibility test procedures.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, quality control procedures, and interview with the laboratory staff, it was determined that the laboratory director failed to be responsible for the overall operation including, but is not limited to the following; to ensure that the quality control programs were established and maintained to assure the quality of laboratory services provided. The findings included: See D-5439, and D-5507