Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0856340	(X3) Date Survey Completed 10/17/2018
Name of Provider or Supplier Corazon C Medina, Md Inc	**Street Address, City, State** 1751 W Romneya Dr, Ste H, Anaheim, 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 records, and interview with the technical consultant and the testing personnel, it was determined that the laboratory failed to follow the manufacturer's calibration verification instructions and performed calibration verification at least once every 6 months 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 performed calibration verifications for its chemistry instrument, ACE Alera by Alpha Wassermann, on 9/17/2017 and on 9/6/2018. b. The laboratory failed to meet the CLIA requirements and follow the rules to perform calibration verification procedures every 6 month. c. The laboratory testing personnel affirmed (10/17/18 @ 13:10) that the laboratory did not follow the CLIA rules to perform calibration verification for chemistry instruments, where the analyte useing less than three levels of calibrators in the laboratory's routine calibration procedures must perform calibration verification for that analyte every 6 months.
D6021	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 quality assessment programs are 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, and interview with the technical consultant, and the testing personnel, it was determined that the laboratory director failed to ensure that quality assessment programs were established and maintained to assure the quality of laboratory services provided. The findings included: See D-5439