Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0881670	02/17/2021
Name of Provider or Supplier	**Street Address, City, State**	
Care Bioclinical Laboratory	16311 Ventura Blvd Ste 888, Encino, 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 records, random patient sampling, lack of documentation for the Beckman Coulter Access 2 Calibration verification, and interviews with the technical supervisor (TS) and testing personnel (TP); it was determined that the laboratory failed to perform and document calibration verification procedures for the year 2020. The findings included: 1. On the day of the survey 02/11/2021 at approximately 11: 30, the TS and TP failed to provide documentation for the calibration verification for

	Beckman Coulter Access 2 instrument for the year 2020. 2. For three (3) out of seven (7) random patient sampling test results reviewed, covering period from 02/25/2020 to 2/11/2021, the laboratory analyzed and reported patient's laboratory tests during the time when the laboratory did not perform calibration verification for the Beckman Coulter Access 2. 3. Based on the laboratory's annual declaration submitted for the year 2020, the laboratory analyzed and reported approximately 17,000 immunoassay tests without performing calibration verification every six months or whenever it is needed. 4. The TS and TP affirmed on 02/17/2021 at approximately 1:25 p.m. that the laboratory failed to perform calibration verification every six months or whenever it is needed.
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 observation, lack of documentation, random patient sampling, and interview with the technical supervisor (TS) and testing personnel (TP); it was determined that the laboratory failed perform quality control on the Kirby-Bauer (KB) antimicrobial susceptibility testing method each day the test was performed. The findings included: 1. On the day of the survey, February 17, 2021, the laboratory lacked the documentation for KB antimicrobial susceptibility use of control organisms for each day the KB antimicrobial susceptibility test was performed. 2. The laboratory did not provide an Individualized Quality Control (QC) Program for KB susceptibility testing a procedure which may be used in the laboratory to detemine organisms QC frequency for the antimicrobial susceptibility testing method. 2. For two (2) out of seven (7) random patient sampling test results reviewed, covering period from 2/25 /2020 to 2/11/2021 the laboratory analyzed and reported patient test results for KB antimicrobial susceptibility during the time when the laboratory did not use control organisms for each day the KB antimicrobial susceptibility tests method was performed. 3. The TS and TP affirmed on 02/17/2021 at approximately 2:00 p.m. that the laboratory was not performing quality control organisms for each day the KB antimicrobial susceptibility test was performed.
D6119	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(6) The technical supervisor is responsible for ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly. This STANDARD is not met as evidenced by: Based on interviews with the technical supervisor and testing personnel, review of:

	policies and procedures, quality control documentation, calibration verification records, and patients' reports; it was determined that the technical supervisor failed to ensure that patient test results were not reported until the test system was functioning properly. See D5439 and D5507.