Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0881670	09/30/2024
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
D0000	A proficiency testing desk review survey was performed on September 30, 2024, the laboratory was found not in compliance with the following CONDITION LEVEL DEFICIENCES: D2016 - 42 C.F.R. 493.803 Condition: Successful participation (proficiency testing); and D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on the review of the Certification and Survey Provider Enhanced Reporting (CASPER) 0155D and American Proficiency Institute (API) records (2023-Q3, 2024-Q1, and 2024-Q2), the laboratory failed to successfully participate in a proficiency

	testing program approved by HHS, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA, the laboratory failed to successfully participate in the subspecialty of Routine Chemistry for the analyte Bilirubin, Total, resulting in subsequent unsuccessful performance. Refer to D2096.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on desk review of Certification and Survey Provider Enchanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and API evaluation reports, the laboratory failed to achieve satisfactory performance for two of three prficiency events in 2024 for analytes: ALT (SGPT), Albumin, AST (SGOT), Ca-total, Cl, Creatinine, Glucose/non-waived, Mg, K, Na, and BUN. The finding include: 1. The laboratory received the following proficiency testing scores: 0% on the 2024 ALT first event 0% on the 2024 ALT second event 0% on the 2024 Albumin first event 0% on the 2024 Albumin second event 0% on the 2024 Alk Phos first event 0% on the 2024 Alk Phos second event 0% on the 2024 AST (SGOT) first event 0% on the 2024 AST (SGOT) second event 0% on the 2024 Ca first event 0% on the 2024 Ca second event 0% on the 2024 Cl first event 0% on the 2024 Cl second event 0% on the 2024 Creatinine first event 0% on the 2024 Creatinine second event 0% on the 2024 Glucose (non-waived) first event 0% on the 2024 Glucose (non-waived) second event 0% on the 2024 Mg first event 0% on the 2024 Mg second event 0% on the 2024 K first event 0% on the 2024 K second event 0% on the 2024 Na first event 0% on the 2024 Na second event 0% on the 2024 Total Protein first event 0% on the 2024 TotalProtein second event 0% on the 2024 BUN first event 0% on the 2024 BUN second event
D2107	ENDOCRINOLOGY CFR(s): 493.843(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on desk review of Certification and Survey Provider Enchanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and API evaluation reports, the laboratory failed to achieve satisfactory performance for two of three prficiency events in 2024 for analytes: Triiodothyronine and TSH. The finding include: 1. The laboratory received the following proficiency testing scores: 0% on the 2024 Triiodothyronine first event 0% on the 2024 Triiodothyronine second event 0% on the 2024 TSH first event 0% on the 2024 TSH second event
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403

	The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the proficiency testing desk review of the CASPER 0155D report API records for 2023-Q3, 2024-Q1, and 2024-Q2 events, the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of CASPER 155 report API records for 2023-3, 2024-1 and 2024-2 events, the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D2096 and D2107.