

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0881670	(X3) Date Survey Completed 05/15/2024
Name of Provider or Supplier Care Bioclinical Laboratory	Street Address, City, State 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
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 review of the Certification and Survey Provider Enhanced Reporting (CASPER) -155D and API - American Proficiency Institute (API) records (2023-3 and 2024-1), the laboratory failed to successfully participate in a proficiency testing program approved by HHS, for each specialty, subspecialty, and test in which the laboratory is certified under CLIA. The laboratory failed to successfully participate in the subspecialty of Bacteriology and the test Bilirubin, Total. Refer to D2020 and D2088.
D2020	BACTERIOLOGY

	CFR(s): 493.823(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and API - American Proficiency Institute (API) report, the laboratory failed to achieve satisfactory performance for two consecutive events (2023 third testing event and 2024 first testing event) for the subspecialty of Bacteriology: The finding include: 60% on the 2023 third event 0% on the 2024 first event A review of the 2023 and 2024 scores from API - American Proficiency Institute confirmed the above findings.
D2088	ROUTINE CHEMISTRY CFR(s): 493.841(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and API - American Proficiency Institute (API) report, the laboratory failed to achieve satisfactory performance for two consecutive events (2023 third testing event and 2024 first testing event) for the analyte Bilirubin, Total (Bili, T): The finding include: 0% on the 2023 third event 0% on the 2024 first event A review of the 2023 and 2024 scores from API - American Proficiency Institute confirmed the above findings.
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 a proficiency testing desk review of the CASPER 0155 report and API records for 2023-3 and 2024-1 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 0155 report and API records for 2023-3 and 2024-1 events, the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D2020 and D2088.