

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2051772	(X3) Date Survey Completed 08/12/2024
Name of Provider or Supplier Healthcare Clinical Laboratory, Inc	Street Address, City, State 5744 San Fernando Rd, Unit 200, Glendale, 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 8/12/2024, the laboratory was found not in compliance with the following CONDITION LEVEL DEFICIENCIES D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing]; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing high complexity testing; laboratory director.
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) - 0155D and AAB-Medical Laboratory Evaluation records (2023-3 and 2024-2), the laboratory failed to successfully participate in a proficiency testing</p>

	<p>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 Hematology for the analyte Antibody Detection resulting in an unsuccessful performance. Refer to D2172.</p>
<p>D2172</p>	<p>UNEXPECTED ANTIBODY DETECTION CFR(s): 493.861(e)</p> <p>Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on desk review of Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and AAB-Medical Laboratory Evaluation reports, the laboratory failed to achieve satisfactory performance for two of three events proficiency events in 2023 and 2024 for analyte Antibody Detection. The finding include 1. The laboratory received the following scores: 0% on the 2023 Antibody Detection third event 0% on the 2024 Antibody Detection second event 2. A review of the 2023 and 2024 proficiency Testing scores from AAB confirmed the above findings.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on a proficiency testing desk review of the CASPER 155 report AAB records for 2023-3 and 2024-2 events, the laboratory director failed to provide overall management and a direction of the laboratory services. Refer to D2172.</p>
<p>D6092</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv)</p> <p>The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of the CASPER 155 report , AAB-Medical Laboratory Evaluation records for 2023-3 and 2024-1 events, the laboratory director failed to provide overall management and a direction of the laboratory services. Refer to D6076.</p>