

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D2051772	<b>(X3) Date Survey Completed</b>  01/26/2022
<b>Name of Provider or Supplier</b>  Healthcare Clinical Laboratory, Inc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2087</b>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Association of Bioanalysts (AAB) proficiency testing (PT) records, randomly chosen patient results' review, and interview with the technical supervisor (TS); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for the following analytes: Chloride, Sodium, and Potassium for the third event of 2021 (Q3-2021). The finding included: 1. Based on review of PT records for the Q3-2021 AAB reported the following unsatisfactory scores: Analyte Score Chloride 0% Sodium 0% Potassium 60% 2. Based on the laboratory testing declaration submitted at the time of the survey on January 26, 2022 the laboratory analyzed and reported approximately 3,898 Routine Chemistry tests for each year during the time the laboratory had unsatisfactory proficiency testing results. 3. The TS affirmed on 01/26,2022at approximately 11:00 a. m. that the laboratory received the above unsatisfactory proficiency testing scores.</p>
<b>D2121</b>	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's American Association of Bioanalysts (AAB) testing records, five (5) random patients sampling, and interview with the technical</p>

supervisor (TS); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Hematology on the third event of 2021 (Q2-2021). The findings included: 1. The AAB proficiency program gave an overall unsatisfactory score of 59 % for Hematology for Q3-2021 which included: Analyte Score WBC 20% RBC 20% Hemoglobin 20% Platelets 20% 2. Based on the laboratory's annual testing declaration submitted on the day of the survey January 26, 2022; the laboratory analyzed and reported approximately 2,134 Hematology samples which included WBC, RBC, Hemoglobin, and platelet counts during the time the laboratory had unsatisfactory proficiency testing results. 3. The TS confirmed on 01/26 /2022 at approximately 11:45 a.m. that the laboratory received the above proficiency score of 59% for Hematology as described in 1.

**D6082**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(1)

The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's records for proficiency testing results and interview with the technical supervisor and laboratory testing personnel on January 26, 2022; it was determined that the laboratory director failed to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of laboratory testing were monitored when processing, testing, and reporting proficiency samples. See D2121 and D2087.