

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2145028	(X3) Date Survey Completed 10/19/2021
Name of Provider or Supplier Cell Diagnostics Inc	Street Address, City, State 1737 E Washington Blvd Ste 5, Pasadena, 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
D2087	<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 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 Total Cholesterol for the second event of 2021 (Q2-2021). The finding included: 1. Based on review of PT records for the Q2-2021 AAB reported the following unsatisfactory scores for Total Cholesterol Event Score 20.0: Sample Reported Grading Range 6 72 74-90 7 105 107-131 8 156 156-191 9 138 139-170 10 177 181-221 2. Based on the laboratory testing declaration submitted at the time of the survey on October 19, 2021 the laboratory analyzed and reported approximately 49,700 Routine Chemistry tests for each year during the time the laboratory had unsatisfactory proficiency testing results. 3. The TS affirmed on 10/19 /2021 at approximately 11:30 a.m. that the laboratory received the above unsatisfactory proficiency testing scores.</p>
D6087	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii)</p> <p>The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory technical supervisor interviews, proficiency test reports</p>

documents for Routine Chemistry, and policies and procedures record review on October 19, 2021; the laboratory director failed to ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. See D2087.