

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1092782	(X3) Date Survey Completed 11/03/2021
Name of Provider or Supplier Newport Childrens Medical Group	Street Address, City, State 1640 Newport Blvd Ste 210, Costa Mesa, 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
D2121	<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 the surveyor's review of the laboratory's records for evaluation of proficiency testing performance from CMS, laboratory proficiency reporting from API (American Proficiency Institute) and an interview with the laboratory Technical Consultant (TC) on 11/3/2021 between 11:00 a.m. and 12:30 p.m., it was determined that there were two unacceptable (below 80 %) proficiency testing (PT) results for RBC and HCT for Cycle 1 in 2019. Findings include: 1. On 11/3/2021, an inspection was conducted between 10:00 a.m. and 12:30 p.m. 2. During a review of the laboratory documentation from API (agency providing the proficiency specimens), it was noted at approximately 11 a.m. that there were two unacceptable PT results for Cycle 1 RBC and HCT on the 2019 proficiency reports. The laboratory utilizes the Abbott Cell-Dyn instrument for Hematology testing. The TC recognized these atypical results. 3. The findings and acceptable ranges were as follows: Analyte: HCT Score: 40% Cycle 1 2019 Sample Actual Result Expected Result (range) HEM-02 16 17-20 HEM-03 43 44-50 HEM-04 29 32-37 Analyte: RBC Score: 20% Cycle 1 2019 Sample Actual Result Expected Result (range) HEM-02 2.00 2.22-2.51 HEM-03 4.70 4.90-5.54 HEM-04 3.46 3.99-4.51 HEM-05 4.85 4.90-5.53 4. The TC affirmed the unacceptable results listed above.</p>