Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1092782	09/09/2025
Name of Provider or Supplier	**Street Address, City, State**	
Newport Childrens Medical Group	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	HEMATOLOGY CFR(s): 493.851(a) (a) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records, and interview with the Technical Consultant (TC) on September 9, 2025, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for PT testing for each analyte for the specialty Hematology in the second event of 2025. The findings included: 1. It was the practice of the laboratory to perform moderate complexity testing in the specialty of hematology and the laboratory enrolled in the American Proficiency Institute (API) proficiency testing (PT) program for hematology using the Abbott Cell-Dyn -1800 Analyzer. 2. According to the API evaluation report, the laboratory received unsatisfactory scores of 20% in the second event of 2025 for White Cell Blood Count (WBC) as follows: Sample Reported Result Exp. Result HEM-06 8.2 6.5-8.1 HEM-07 20.6 16.7-20.5 HEM-08 21.8 16.6-20.4 HEM-09 2.5 1.9-2.4 HEM-10 12.2 9.8-12.1 3. On September 9, 2025, at approximately 11:00 am, the TC confirmed that the laboratory received the above unsatisfactory proficiency scores, with test values exceeding the expected range, indicating a potential systematic error. 4. The laboratory's testing declaration form, signed by the laboratory director on August 22, 2025, stated that the laboratory performed approximately 1296 hematology tests annually.