Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 05D1092782	**(X3) Date Survey Completed** 10/25/2019
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	HEMATOLOGY CFR(s): 493.851(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 first quarter (Q1-2019) of the American Proficiency Institute (API) proficiecy testing (PT) result reports, and interview with the laboratory technical consultant (TC), it was determined that the laboratory failed to atained a score of at least 80 percent of acceptable responses for Red Blood Cell counts (RBC) and Hematocrit (HCT). The findings included: a. The laboratory used Abbott CElldyn 1800 to perform Complete Blood Cell Counts (CBC) including but not limited to RBC and HCT for its patient blood speciemes. b. The laboratory enrolled its PT program with the American Proficiency Institute (API) PT provider in order to meet the CLIA requirement for Evaluation of proficiency testing performance annually. c. The laboratory attained scores of 20 % and 40% for RBC and HCT respectively in the Q1-2019 API PT event which was unsatisfactory analyte performance for the testing event. d. The laboratory performed RBC and HCT in approximately 100 monthly. e. The TC affirmed (10/25/2019 @ 11:30 AM) that the laboratory attained scores of 20 % and 40% for RBC and HCT respectively in the Q1-2019 API PT event which was unsatisfactory analyte performance for the testing event.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

	This STANDARD is not met as evidenced by: Based review of the laboratory patient test result reports from its EMR (electronic medical records) system, and its Critical Value Reporting Policy and Procedure (CP&P), and interview with the laboratory techincal consultant (TC) and the laboratory personnel, it was determined that the laboratory failed to follow its written policies and procedures (P&P) for an ongoing mechanism to monitor, quality assess the patient's test result reports, and, when indicated, correct problems identified in the postanalytic systems. The findings included: a. The laboratory has established its CP&P stated: "The critical value must be circled on the report and verified by repeat analysis" b. The laboratory's CP&P established its critical values as the followings: less than greater than WBC: 1.5 x 1000 16 x 1000 Hgb: 9.0 gm/dL 20.0 gm/dL HCT 20 % 55% Platelets 50 x 1000 550 x 1000 c. Review of five (5) patientt CBC test result reports between 03/25/2019 and 04/19/2019 d. One of the 5 patient test result reports, tested on 4/9/2019 JB, indicated that the WBC result was 16.9 x 1000 which was greater than critical value. e The laboratory did not indicated and documented the WBC test result of 16.9 x 1000 been repeated in their EMR record. f. The laboratory personnel affiremd (10/25/2019 @ 10:35 am) that the laboratory failed to follow its Critical Value Reporting Policy and Procedure.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiecy testing (PT) result reports between 2018 thru 2019 events, and interview with the laboratory technical consultaant (TC), it was dedtermined that the laboratory director failed to ensure that the proficiency testing samples were tested as required to ensure the accuracy of the testing system annually. The findings included: a. The laboratory enrolled its PT program with API for CBC testing and attained scores of 20 % and 40% for RBC and HCT respectively in the Q1-2019 API PT event which was unsatisfactory analyte performance for the testing event, see D-2121.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by:

	Based on observation of the laboratory operations, review of the laboratory's testing result records, and interview with the laboratory technical consultant (TC) and the laboratory personnel, it was determined that the laboratory director failed to ensure that the quality assessment program was maintained to assure the quality of laboratory services provided. The findings included: a. The laboratory failed to ensure the accuracy of the testing system resulted from the failure of the Q1 2019 API PT event, see D-2121. b. The laboratory failed to follow its "Critical Value Reporting Policy and Procedure", see D-5891.