

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2064377	(X3) Date Survey Completed 04/30/2018
Name of Provider or Supplier Newport Children Medical Group At Mission	Street Address, City, State 26800 Crown Valley Pkwy Ste 510, Mission Viejo, 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 2016/events 1 & 2 proficiency testing reports from CMS (report 155D, Individual Laboratory Profile) and API (American Proficiency Institute), laboratory proficiency testing records for HDL Cholesterol and Glucose, and patients test reports; and interview with the Technical Consultant, the laboratory failed to attain scores of at least 80%, constituting unsatisfactory analyte performances. Findings include: a. CMS and CAP reported the unsatisfactory scores of 50% as follows: Event Analyte Unacceptable results ----- 2016: 1 HDL 1 out of 2 2016: 2 Glucose 1 out of 2 b. The Technical Consultant affirmed (4/30/18) the aforementioned unacceptable results and scores; and thus, unsatisfactory analyte performances. c. The reliability and quality of results reported using the Alere Cholestech LDX analyzer (Waived) could not be assured. 1) HDL Based on the stated estimated annual test volume, the laboratory reported approximately 1 HDL result each month during the timeframe January to April 2016. A few examples are as follows: Date reported ID ----- 3/23/16 MP 3/25/16 MM 4/21 /16 AR 4/28/16 YR 2) Glucose Based on the stated estimated annual test volume, the laboratory reported approximately 12 Glucose results each month during the timeframe of June to August 2016. A few examples are as follows: Date reported ID ----- 6/08/16 GV 6/20/16 CE 7/17/16 SP 8/08/16 BV</p>