Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0707237	01/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Palo Alto Medical Foundation	301 Old San Francisco Rd Level A, Sunnyvale, 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	ROUTINE CHEMISTRY CFR(s): 493.841(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 reviews of 2017 proficiency testing reports from CMS (report 155D, Individual laboratory profile) and CAP (College of American Pathologists), laboratory proficiency testing records, and patients test reports; and interview with the Technical Consultant, the laboratory failed to attain a score of at least 80% for Sodium (Na) for the 2nd event of 2017, constituting unsatisfactory analyte performance. Findings include: a. CMS and CAP reported the score of 40% ; and thus, unsatisfactory testing for Sodium. b. The laboratory reported 3 unacceptable results out of 5. All three unacceptable results failed to meet CAP's lower limits of acceptability. c. The Technical Consultant affirmed (1/25/18) the aforementioned unacceptable results and unsatisfactory score. d. The reliability and quality of results reported for Sodium during the timeframe June to September 2017 could not be assured. Based on the stated estimated annual test volume, the laboratory reported approximately 1,526 results each month. A few examples are as follows: Date Order number ---------- 6/08/17 865916974 6/26/17 868502239 7/03/17 869500738
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	This STANDARD is not met as evidenced by: Based on review of 2017 CAP (College of American Pathologists) proficiency testing reports, laboratory proficiency testing records, and patients test reports for Neonatal Direct Bilirubin; and interview with the Technical Consultant, the laboratory failed to verify the accuracy of testing for Neonatal Direct Bilirubin. Findings include: a. The laboratory chose to participate in CAP's proficiency testing program "NB" as the means to satisfy the requirement to verify the accuracy of testing for Neonatal Direct Bilirubin. b. For 1st event/2017, laboratory proficiency testing records revealed the laboratory reported 1 unacceptable result out of 2; and thus, accuracy was not verified. c. The Technical Consultant affirmed (1/25/18) the aforementioned results. d. The reliability and accuracy of results reported for Neonatal Direct Bilirubin could not be assured. Based on the stated estimated annual test volume, the laboratory reported approximately 171 Direct Bilirubin results for Neonates and adults each month during the timeframes January to May 2017. A few examples are as follows: Date Order number ---------- 3/08/17 851955975 4/28/17 859859745 5/19/17 863306354