Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0062682	01/23/2018
Name of Provider or Supplier	**Street Address, City, State**	
Palo Alto Medical Foundation Clinical Lab	795 El Camino Real, Lee Bldg, Palo Alto, 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 2016/2nd event proficiency testing reports from CMS (report 155D, Individual Laboratory Profile) and CAP (College of American Pathologists, program CGL) for PTT (Partial Thromboplastin Time) and PT (Prothrombin Time) testing in coagulation, laboratory proficiency testing records, and tests reports for patients, including those on Coumadin and/or Heparin; and interview with the Technical Consultant, the laboratory failed to obtain satisfactory scores of at least 80% Findings include: a. CMS and CAP reported scores for 2016: event 2 as follows: PTT ... ...20% PT ... ...20% INR ... ...20% b. Laboratory proficiency testing records revealed the laboratory reported 4 unacceptable results out of 5 for each analyte on 5/14/16. c. The Technical Consultant affirmed (1/23/18) the aforementioned unsatisfactory scores; and thus, unsatisfactory test performances. d. The reliability and quality of results reported during the timeframe May - August 2016 could not be assured. Based on the laboratory's stated annual test volumes, the laboratory reported approximate monthly volumes of 86 PTT and 529 PT with INR results each month A few examples are as follows: Date Test volume Accession ---------- 5/11/16 3 L2810411786 6/21/16 2 L2820768285 7/29/16 2 L2831029006 8/18/16 2 L2840671473
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 2016-2017 CAP (College of American Pathologists) proficiency testing reports, laboratory proficiency testing records, and patients test reports for Neonatal Direct Bilirubin; the lack of laboratory documents for Reticulocyte counts, review of patients test reports for Reticulocytes; and interview with the Technical Consultant, the laboratory failed to verify the accuracy of testing for Neonatal Direct Bilirubin and Reticulocytes. Findings include: a. The laboratory chose to participate in CAP's proficiency testing programs as the means to satisfy the requirement to verify the accuracy of testing for Neonatal Direct Bilirubin and Reticulocyte counts. 1) Neonatal Direct Bilirubin, program "NB" i. The laboratory reported 1 unacceptable result out of 2; and thus, accuracy was not verified for multiple events as follows: 2016: event B, on 6/20/16 2016: event C, on 10/18/16 2017: event B, on 6/21/17 ii. The Technical Consultant affirmed (1/23/18) the aforementioned results. iii. 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 74 Neonatal Direct Bilirubin results each month during the timeframes June to December 2016, and June to September 2017. A few examples are as follows: Date Sample number ---------- 6/20/16 L2820725125 7/30/16 L2831057529 8/13/16 L2840489499 9/17/16 L2850606966 10/18/16 L2860651365 2) Reticulocytes, program "RT" i. Laboratory proficiency testing records and CAP proficiency testing reports revealed the laboratory participated in the 2nd event of 2016 (September). However, the laboratory was unable to provide CAP documents or laboratory proficiency testing records for the 1st event of 2016 (January). ii. The Technical Consultant affirmed (1/23/18) the aforementioned results; and thus, the laboratory failed to at least twice annually verify the accuracy of test counts for Reticulcytes. iii. The reliability and accuracy of results reported for Reticulcytes could not be assured. Based on the stated estimated annual test volume, the laboratory reported approximately 64 results each month during the timeframes January to August 2016. A few examples are as follows: Date Sample number ---------- 2/03/16 L2780131425 3/04/16 L2790166825 4/15 /16 L2800599810 5/20/16 L2810757749 6/10/16 L2820372229 7/18/16 L2830591627 8/15/16 L2840526496
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on survey findings and deficiencies cited, the Technical Consultant is herein cited for deficient practice in providing technical and scientific oversight of the laboratory. Findings include: a. The laboratory had issues with verifying test accuracies. See D5217.