Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1066402	04/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Palo Alto Medical Foundation -	4050 Dublin Blvd, Dublin, 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
D2056	VIROLOGY CFR(s): 493.831(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of 2016: 3rd event proficiency testing reports from CMS (report 155D, Individual Laboratory Profile) and CAP (College of American Pathologists), laboratory proficiency testing records, patients test reports for RSV (Repiratory Syncytial Virus antigen); and interview with Technical Consultant-1 and Technical Consultant-2, the laboratory failed to attain an overall testing event score of at least 80% in Virology, constituting unsatisfactory performance. Findings include: a. CMS and CAP reported the unsatisfactory score of 74% in Virology, based on the score of 40% attained for RSV direct antigen testing. b. Laboratory proficiency testing records revealed 3 unacceptable results out of 5 for RSV direct antigen. c. The Technical Consultants affirmed (4/05/18) the aforementioned unacceptable results for RSV direct antigen; and thus, unsatisfactory RSV test performance. d. The reliability and quality of results reported could not be assured. Technical Consultants affirmed (4/16 /18) the laboratory reported 42 RSV direct antigen results during the timeframe November to December 2016. A few examples are as follows: Date Order ---------- 11/01/16 599135906 11/16/16 695353076 11/29/16 699824545 12/02/16 698028498 12/15/16 706396319 12/19/16 706759935 .
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: 1st event proficiency testing report from CAP (College of American Pathologists), laboratory proficiency testing records, and patients test reports for Neonatal Direct Bilirubin; and interview with Technical Consultant-1 and Technical Consultant-2, 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 the 1st event of 2017, the laboratory reported 1 unacceptable result out of 2; and thus, accuracy was not verified. c. Technical Consultant-1 and Technical Consultant-2 affirmed (4/05/18) the aforementioned results. d. The reliability and quality of results reported for Neonatal Direct Bilirubin could not be assured. Based on the Technical Consultants affirmation (4/16/18) of the annual test volume of 38 for 2017, the laboratory reported approximately 3 Neonatal Direct Bilirubin results each month during the timeframe January to May 2017. A few examples are as follows: Date Order ---------- 3/04/17 735854096 3/24/17 744129267 4/11/17 750740816 4/11/17 750740817 4/28/17 745494587 5/11/17 759206677 5/11/17 759206678 5/20/17 765751348 5/20/17 765751349 .
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on observation of the Stago Compact coagulation analyzer (serial number 0128740), review of 2016 - 2018 laboratory documents for verifying calibrations, and patients test reports, the lack of laboratory documents, and interview with Technical Consultant-2 (Testing Person), the laboratory failed to perform and document procedures verifying instrument calibrations for D-Dimer at least once every 6 months. Findings include: a. Laboratory documents for verifying D-Dimer calibrations revealed procedures were performed as follows: April 2016 October 2016 June 2017 January 2018 b. The laboratory failed to provide documents of verifications

	performed within 6 months following October 2016 and June 2017. c. Technical Consultant-2 (Testing Person) affirmed (4/05/18) the aforementioned dates; and thus, the laboratory failed to verify D-Dimer calibrations at least once every 6 months. 4) The reliability and quality of results reported could not be assured. Based on the reported estimated annual test volume, the laboratory reported approximately 17 results for D-Dimer each month, specifically during April and May 2016, and December 2017. Examples are as follows: Date Order ---------- ---------- 4/22/16 577808755 5/09/16 623514441 12/09/17 841621716