

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2096854	(X3) Date Survey Completed 02/23/2018
Name of Provider or Supplier Palo Alto Medical Foundation	Street Address, City, State 15400 Los Gatos Blvd, Los Gatos, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>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 and ESR (Erythrocyte Sedimentation Rate); and interview with the Technical Consultant, the laboratory failed to verify the accuracy of testing for Neonatal Direct Bilirubin and ESR. 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 ESR. 1) Neonatal Direct Bilirubin, program "NB" i. For 1st event/2017, the laboratory reported 1 unacceptable result out of 2; and thus, accuracy was not verified. ii. The Technical Consultant affirmed (1/24/18) 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 282 Direct Bilirubin results for Neonates and adults each month during the timeframe January to May 2017. A few examples are as follows: Date Accession ----- 3/14/17 T195266 4/02/17 X340237 5/09/17 T447843 2) ESR, program "ESR" i. The laboratory reported 1 unacceptable result out of 3; and thus, accuracy was not verified for consecutive events as follows: 2016: event B (September) 2017: event A (May) ii. The Technical Consultant affirmed (1/23/18) the aforementioned results. iii. The reliability and accuracy of ESR results reported could not be assured. Based on the stated estimated annual test volume, the laboratory reported approximately 195 results each month during the timeframe September 2016</p>

to May 2017. A few examples are as follows: Date Accession / Order
----- 9/21/16 W798815 10/11/16 T373825 11/14/16
M146938 1/09/17 M394425 2/07/17 T22059 3/07/17 851884090