

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0900020	(X3) Date Survey Completed 09/18/2019
Name of Provider or Supplier Castle Family Health Centers, Inc At Castle	Street Address, City, State 3605 Hospital Rd, Atwater, 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	<p>HEMATOLOGY CFR(s): 493.851(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 observation of a Sysmex 600 series analyzer for coagulation testing, review of 2018 proficiency testing reports from CMS (report 155D, Individual Laboratory Profile) and AAB (American Association of Bioanalysts), laboratory proficiency testing records, and patients results; and interview with laboratory personnel, it was revealed that the laboratory failed to attain a score of at least 80% for Prothrombin Time (Coagulation test). Findings included: a. CMS and AAB reported the unsatisfactory score of 60% for event 2 of 2018 for Prothrombin Time. b. Laboratory proficiency testing records showed all 5 results were low compared to to the Mean, and that 2 were unacceptable: Sample Lab result Mean Acceptable Range ----- 1 16.9 19.95 17.0 - 22.9 2 11.0 12.08 10.3 - 13.9 3 22.0 26.19 22.3 - 30.1 4 10.4 11.06 9.4 - 12.7 5 10.3 11.65 9.9 - 13.4 b. Laboratory personnel affirmed (8/15/19 at 3pm) the aforementioned findings. c. The reliability and quality of results reported for patients could not be assured when proficiency testing indicated testing was unsatisfactory and results were too short. A few examples selected at random from the timeframe May - September 2018 were as follows: Date Spec # ----- 5/18/18 0518 : CG00001R 6 /20/18 0620 : CG00003R 7/06/18 0706 : CG00005R 8/27/18 0827 : CG00002R 9/10 /18 0910 : CG00002R .</p>