

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2146683	(X3) Date Survey Completed 04/07/2022
Name of Provider or Supplier Sutter Gould Medical Foundation	Street Address, City, State 445 W Eaton Ave, Ste 1121, Tracy, 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 the surveyor's review of the laboratory's records for evaluation of proficiency testing performance and an interview with laboratory personnel (LP) on 4/7/22 between 8:30 a.m. and 10:00 a.m, it was determined that there were proficiency testing (PT) scores below 80 % for two parameters during two testing cycles. The issues related to Hematocrit for cycle Q1 in 2020 and Erythrocytes for cycle Q3 in 2021. Findings include: 1. On 4/7/22, an inspection was conducted between 8:30 a.m. and 10:00 a.m. 2. During a review of the laboratory documentation from AAB (American Association of Bioanalysts- the agency providing the proficiency specimens), it was noted at approximately 9:00 a.m. that the laboratory had unacceptable Hematology results as indicated below. For each of the two items listed, the section score was 60 %. The testing was completed on a Sysmex pocHi-100i device. 3. The findings and acceptable ranges were as follows: Cycle Q1 2020 Test: Hematocrit (Hct) Sample Actual Result Expected Result (range) 3 18.1 18.3-20.6 4 31.9 32.4-36.5 Cycle Q3 2021 Test: Erythrocytes Sample Actual Result Expected Result (range) 12 4.36 3.83-4.32 13 6.24 5.39-6.07 4. The LP recognized the above results.</p>