

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0670976	(X3) Date Survey Completed 03/11/2026
Name of Provider or Supplier Sutter Pacific Medical Foundation	Street Address, City, State 2324 Sacramento Street Suite 111, San Francisco, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: . Based on review of patient specimen test records and laboratory proficiency testing records for five consecutive events: 2024: Events 2 & 3, and 2025: Events 1, 2 & 3; and interview with Testing Person-2 (CMS209 Laboratory Personnel Report (CLIA), 2/04/26) and three Technical Consultants, it was determined that the laboratory failed to include proficiency samples into the regular workflow to be tested by personnel routinely testing patients specimen. Findings included: 1. All Proficiency samples were tested by Testing Person-1 and Testing Person-2 for 5 out of 5 consecutive events including 2024, Event 2, to 2025, Event 3. 2. During the timeframe July 2024 - November 2025: 9 out of 13 records reviewewd documented Patients specimen were tested by Testing Persons 3, 4, 5, and two traveling nurses, as follows: Date Testing Person ----- 7/15/24 4 7/17/24 3 8/02/24 4 8/02/24 5 9/06/24 5 11/04/24 4 1/24/25 4 3/21/25 Travel Nurse-1 11/14/25 LC-2 3. The three Technical Consultants and Testing Person-2 affirmed (3/11/26 at 4:00 PM) the aforementioned records and thus, that the proficiency test samples were not integrated into the routine workloads. .</p>
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>(e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and</p>

complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

This STANDARD is not met as evidenced by:

. Based on observation of the Beckman Coulter DxH 520 (serial number 77370015) hematology analyzer, the lack of laboratory records, and interview with Testing Person-2 and three Technical Consultants, it was determined that the Laboratory Director was deficient in the practice of ensuring testing personnel had records of Training and demonstrated preanalytic, analytic, and postanalytic phases of testing, with instrument printouts (raw data) of reliable results, and initial evaluations of test performance. Findings included: 1. The laboratory failed to provide Beckman Coulter DxH 520 training records with instrument printout of reliable results and initial evaluation for Testing Person-2. 2. For 5 out of 5 Testing Persons: Testing Person-2 and the three Technical Consultants affirmed (3/11/26 at 5:00 PM) there were no records of training for the Beckman Coulter DxH 520, no records of demonstrated testing, no records of obtaining reliable results, and no initial evaluations.