

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0707237	(X3) Date Survey Completed 10/09/2025
Name of Provider or Supplier Palo Alto Medical Foundation	Street Address, City, State 301 Old San Francisco Rd Level A, Sunnyvale, 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
D2104	<p>ENDOCRINOLOGY CFR(s): 493.843(d)</p> <p>(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the College of American Pathologists (CAP) proficiency testing (PT) records for the second event of 2023 (Q2-2023), documentation of corrective actions, and interviews with the technical consultant (TC), laboratory supervisor (LS), and quality assurance officer (QAO); it was determined that the laboratory failed to submit the PT results within the timeframe specified by CAP. The findings include: 1. The review of the CAP PT records indicated that the laboratory received an unsatisfactory score of 0% for the free thyroid (FT4) analyte for the Q2-2023 event, with code 42 noted on the score sheet indicating "no result assigned due to absence of response." 2. Review of the PT documentation revealed that the laboratory performed the test but failed to submit within the timeframe specified by the PT agency. 3. The TC, LS, and QAO affirmed by interviews that the laboratory obtained the unsatisfactory score of 0% for FT4 analyte as mentioned in statements above. 4. According to the declaration form (Lab-144) submitted at the time of survey, the laboratory performed and reported 2,744 patient test samples for FT4 analyte including the time when the unsatisfactory score was obtained. Thus, the quality and reliability of patient test results reported cannot be assured.</p>
D6036	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413</p> <p>The technical consultant is responsible for the technical and scientific oversight of the</p>

laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section.

This STANDARD is not met as evidenced by:

Based on the surveyor's findings on October 9, 2025, and interviews with technical consultant, laboratory supervisor, and quality assurance officer; this deficiency is hereby cited due to the technical consultant's failure to provide technical and scientific oversight of the laboratory. The findings include: 1. Unsatisfactory proficiency testing score for Endocrinology. See D2104