

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0606752	(X3) Date Survey Completed 03/13/2024
Name of Provider or Supplier Palo Alto Medical Foundation	Street Address, City, State 2025 Soquel Ave, Santa Cruz, 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
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyors' observation during the laboratory tour and interviews with the technical supervisor (TS) and testing personnel (TP), the laboratory failed to label reagents and solutions for preparation and expiration dates in throughout the laboratory. The findings included: 1. Based on the surveyor's observation during the laboratory's tour on March 13, 2024, at approximately 3:46 p.m.; no opening, preparation, or expiration date labels were used or documented for the reagents and solutions (ex: bleach, methanol, lens cleaner, diluents and distilled water). 2. The TS and TP affirmed in an interview conducted 3/13/2024, at approximately 3:46 p.m. that the reagents and solutions mentioned in statement 1 were not labeled with the opening, preparation, and expiration dates or documented. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 1,717,041 test samples.</p>
D5815	<p>TEST REPORT CFR(s): 493.1291(h)</p> <p>When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing.</p>

This STANDARD is not met as evidenced by:
Based on review of laboratory's policies and procedures, patient test records review from March 13, 2024, and interview with the technical supervisor (TS); it was determined that the laboratory failed to have a policy for turn-around time (TAT) for all tests performed in the laboratory. 1. The laboratory failed to provide TAT of testing for six (6) out of six (6) randomly chosen patients at the time of the survey (March 13, 2024). The laboratory did not provide a TAT policy which may adversely impact patient management. 2. The laboratory TS on March 13, 2024, at approximately 4:10 p.m. affirmed that the laboratory did not have a TAT policy to notify any delay on testing to the health care providers. 3. The laboratory's testing declaration form, signed by the laboratory director on 3/8/2024, stated that the laboratory performs 1,717,041 tests annually.

D6082

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(1)

The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

This STANDARD is not met as evidenced by:
Based on the surveyor's review of the laboratory's records and interviews with the laboratory's technical supervisor (TS) and testing personnel (TP) on March 13, 2024; it was determined that the laboratory director is cited herein due to failure to ensure that several aspects of the preanalytic and analytic phases of the laboratory testing were monitored. See D5415 and D5815.