

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0606752	(X3) Date Survey Completed 04/24/2019
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
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(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 the Siemens Vista 500 chemistry analyzers (serial numbers DV330692 and DV370130), reviews of Event 3, 2017, proficiency testing reports from CMS (report 155D, Individual Laboratory Profile) and CAP (College of American Pathologists), laboratory proficiency testing records, and patients test records; and interview with laboratory personnel, the laboratory failed to attain a score of at least 80%, constituting unsatisfactory testing for Chloride (Cl). Findings included: a. CMS and CAP reported the score of 40% based on 3 unacceptable results out of 5: PT sample Lab result Mean result ----- CHM -12 95 101.7 CHM -13 107 116.3 CHM -14 95 101.6 b. Laboratory personnel, including the Technical Consultant, affirmed (4/24/19 at 5pm) the aforementioned findings; and thus unsatisfactory testing for Chloride. c. The reliability and quality of results reported could not be assured when testing was unsatisfactory. Based on the stated annual test volume, the laboratory reported approximately 5,986 Cl results each month during the timeframe October - December 2017. A few examples selected at random are as follows: Date (patients tested) one example ID ----- 10/21/17 (65) 55665364 10 /22/17 (9)56327060 10/23/17 (209)56014145 . .</p>
D2109	<p>TOXICOLOGY CFR(s): 493.845(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte</p>

in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:

Based on observation of the Siemens Vista 500 chemistry analyzers for toxicology testing, reviews of Event 2, 2017, proficiency testing reports from CMS (report 155D, Individual Laboratory Profile) and CAP (College of American Pathologists), laboratory proficiency testing records, and patients test records; and interview with laboratory personnel, the laboratory failed to attain a score of at least 80%, constituting unsatisfactory testing for Gentamicin. Findings included: a. CMS and CAP reported the score of 60% based on 2 unacceptable results out of 5: PT sample Lab result Acceptable ----- CHM - 09 10.1 2.3 - 3.9 CHM - 10 3.2 7.3 - 12.2 b. Laboratory personnel, including the Technical Consultant, affirmed (4/24/19 at 5pm) the aforementioned findings; and thus unsatisfactory testing for Gentamicin. c. The reliability and quality of results reported could not be assured when testing was unsatisfactory. Based on the stated annual test volume, the laboratory reported approximately 8 results for Gentamicin during the timeframe June - August 2017.

D2121

HEMATOLOGY

CFR(s): 493.851(a)

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.

This STANDARD is not met as evidenced by:

Based on observation of the Stago Compact coagulation analyzer, reviews of Event 2, 2018, proficiency testing reports from CMS (report 155D, Individual Laboratory Profile) and CAP (College of American Pathologists), laboratory proficiency testing records, and patients test records; and interview with laboratory personnel, the laboratory failed to attain scores of at least 80%, constituting unsatisfactory testing for PT and PTT (Prothrombin Time; Partial Thromboplastin Time). Findings included: a. CMS and CAP reported scores of 20% for both PT and PTT based on 4 unacceptable results out of 5 for each analyte. b. Laboratory personnel, including the Technical Consultant, affirmed (4/24/19 at 5pm) the aforementioned findings; and thus unsatisfactory testing for PT and PTT. c. The reliability and quality of results reported could not be assured when testing was unsatisfactory. Based on the stated annual tests volumes, for the timeframe May - August 2018, the laboratory reported approximately 2,085 PT and 416 PTT results. Examples include the following: Date (patients tested) one example ID ----- 5/25/18 (6) F1609545 5/26/18 (2)51333048

D2123

HEMATOLOGY

CFR(s): 493.851(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on

proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

Based on observation of the Stago Compact coagulation analyzer, reviews of Event 2, 2017, proficiency testing reports from CAP (College of American Pathologists) and patients test records; the lack of laboratory proficiency testing records, and interview with laboratory personnel, the laboratory failed to participate for Fibrinogen, constituting unsatisfactory testing. Findings included: a. For 5 of 5 samples shipped on 5/15/17 for evaluation on 7/10/17, CAP received no results from the laboratory and reported Code 11 based on the laboratory's response, "Unable to analyze". b. The laboratory was unable to provide for review records documenting problems with instrument, reagents or control materials that prevented testing of Fibrinogen from date of receipt of the CAP samples in May 2017 to deadline date for reporting in July 2017. c. Test records revealed patients specimen were tested for Fibrinogen during the timeframe May - July 2017: Month (patients tested) Date/ one example ID
----- May 2017 (3)5/25/17...
54869108 June 2017 (9)6/21/17...59580725 July 2017 (13)7/20/17...56081659 d. Laboratory personnel, including the Technical Consultant, affirmed (4/24/19 at 5pm) the aforementioned findings constituting the failure to participate in proficiency testing, resulting in a score of 0% for Fibrinogen and thus, unsatisfactory testing. c. The reliability and quality of results reported could not be assured in the absence of participating in proficiency testing. During the timeframe May - August 2017, the laboratory reported 25 Fibrinogen results. .

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on observation of two Siemens Vista 500 analyzers for chemistry, endocrinology, and toxicology; review of laboratory records verifying test

calibrations, the lack of documents, and interview with laboratory personnel, the laboratory failed to perform calibration verification procedures at least once every 6 months in 2018 to 2019. Findings included: a. Laboratory records reviewed on 4/24 /19 documented calibrations were verified for each analyzer as follows: Vista 500 -A Vista 500 - B ----- June 2017 December 2017 December 2017 January 2018 June 2018 March 2018 August 2018* June 2018 March 2019 August 2018* April 2019 b. The laboratory was unable to provide for review documents verifying each analyzer's calibrations at least once within 6 months after August 2018 (*). c. Laboratory personnel, including the Technical Consultant, affirmed (4/24/19 at 5:30pm) the aforementioned lack of laboratory records; and thus, the laboratory's failure to verify calibrations at least once every 6 months after August 2018. d. The reliability and quality of results reported could not be assured in the absence of timely verifications of instrument calibrations. Based on the stated annual tests volumes, for the timeframe September 2018 - February/March 2019, the laboratory reported the approximate test volumes as follows: Results ----- Chemistry 656,786 Endocrinology ... 22,416 Toxicology 759 .

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:
Based on observation of two Siemens Vista 500 analyzers for chemistry, endocrinology, and toxicology testing, patients tests records and instruments records reviewed on 4/24/19, the lack of laboratory records, and interview with laboratory personnel, it was determined that the laboratory failed to twice a year evaluate and define the relationship between test results for both analyzers. Findings included: a. The second Vista 500 (B) had been put into routine use after February 2017; however, the laboratory failed to provide for review records comparing it's results to the first Vista 500 (A) a second time in 2017. b. Laboratory personnel, including the Technical Consultant, affirmed (4/24/19 at 6pm) the aforementioned lack of records; and thus the failure to twice a year evaluate and define the relationship between test results for both analyzers. c. The reliability and quality of results between analyzers used interchangeably could not be assured in the absence of comparative studies. Based on the stated annual tests volumes, the laboratory in 2017 reported the following estimated test volumes: Routine chemistry1,125,920 Endocrinology 38,429 Toxicology1,302