

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2007863	(X3) Date Survey Completed 04/22/2019
Name of Provider or Supplier Sutter Bay Medical Foundation	Street Address, City, State 2850 Commercial Crossing, 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
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 observation of the Sysmex pocH-100i hematology analyzer (serial number G3843), reviews of proficiency testing reports from CMS (report 155D, Individual Laboratory Profile) and API (American Proficiency Institute), laboratory proficiency testing documents, and patients tests records; and interview with the Technical Consultant, the laboratory failed to attain a score of at least 80% for WBC Differential and Monocyte constituting unsatisfactory analyte performance for 2017-1st event and 2018- 3rd event. Findings included: a. Event 1, 2017 1) CMS and API reported the score of 60% for WBC Differential based on the laboratory's score of 0% for Monocytes. 2) The Technical Consultant affirmed (4/22/19 at 4:00pm) the aforementioned unsatisfactory proficiency testing scores for Monocytes and Differentials. 3) The reliability and quality of results reported for Differentials and Monocyte could not be assured in the absence of satisfactory testing. Based on the reported estimated annual tests volumes, the laboratory reported approximately 3,900 Differentials results during the timeframe January to June 2017. Examples included: Date Specimen ID ----- 1/19/17 55718836 2/13/17 51239475 3/27/17 55632673 4/06/17 61598852 5/11/17 55701283 6/12/17 55687108 b. Event 3, 2018 1) CMS and API reported the score of 60% for Monocytes. 2) The Technical Consultant affirmed (4/22/19 at 4:00pm) the aforementioned unsatisfactory score for Monocytes. 3) The reliability and quality of results reported for Monocytes could not be assured in the absence of a satisfactory score. Based on the reported estimated annual tests volumes, the laboratory reported approximately 2,600 Monocyte results during the timeframe November 2018 to February 2019. Examples included: Date Specimen ID ----- 11/01/18 52018122 12/27/18 55719044 .</p>

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of laboratory proficiency testing records, the lack of records, and interview with the Technical Consultant, the laboratory failed to complete activities assessing failure in testing. Findings included: a. Laboratory documents for event 1, 2017, proficiency testing stated that additional proficiency samples would be obtained for re-testing to investigate the cause for the unsatisfactory test performance. b. The laboratory was unable to provide for review documents for re-testing. c. The Technical Consultant affirmed (4/22/19 at 4:00pm) the aforementioned lack of records; and thus the laboratory failed to follow through with assessing and correcting test performance problem(s) identified by proficiency testing. d. The reliability and quality of patients results reported could not be assured in the absence of assessing and correcting problem(s) in hematology testing. Based on the stated annual estimate, the laboratory reported approximately 46,800 hematology results each year. .

D6019

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iv)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on review of laboratory proficiency testing records for Event 1, 2017, the lack of documents for quality assessment, and the deficiency cited (D5791), the Laboratory Director is herein cited for deficient practice in providing overall administration of the laboratory and ensuring corrective actions when any proficiency testing results are found to be unacceptable or unsatisfactory. Findings included: a. Under the Laboratory Director's administration the laboratory was allowed to fail to follow through with assessing and correcting problem(s) in proficiency testing. .

D6043

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(5)

(b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

This STANDARD is not met as evidenced by:

Based on review of laboratory proficiency testing records for Event 1, 2017, the lack

of documents for quality assessment, and the deficiency cited (D5791), the Technical Consultant is herein cited for deficient practice in responsibility for resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications. Findings included: a. The Technical Consultant, in 2017, failed to follow through with resolving technical problems and ensuring remedial actions were taken when testing deviated from established performance specifications.