

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2091424	(X3) Date Survey Completed 03/06/2020
Name of Provider or Supplier Orange County Vascular & Endovascular	Street Address, City, State 11190 Warner Ave Ste 408, Santa Ana, 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 review of the laboratory's proficiency testing (PT) test result reports, and interview with the laboratory testing personnel, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Protime test in each testing event was unsatisfactory analyte performance for the testing event. The findings included: a. The laboratory used i-Stat instrument to perform Protime (Ptm) testing and enrolled with API (American Proficiency Institute) PT program to verify the accuracy of the testing system annually. b. The laboratory attained a score of 40% for PTm testing in the 3rd 2019 PT events which was unsatisfactory analyte performance for the testing event. c. The laboratory performed PTm in approximately 20 patient samples each month. d. The laboratory affirmed (03/06/2020 @ 10:45 AM) that a score of 40% for PTm testing in the 3rd 2019 PT events was unsatisfactory analyte performance for the testing event.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p>

This STANDARD is not met as evidenced by:
 Based on review of the laboratory's validation records for i-Stat instrument, and interview with the laboratory personnel, it was determined that the laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (A) Accuracy, (B) Precision, (C) Reportable range of test results for the test system, (D) verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. The findings included: a. One of the i Stat instrument validation records, Alternate (Quantitative) Method Comparison for Protime (Ptm), presented three graphics of Scatter Plot, Bias, and Percent Bias. b. Scatter Plot showed X Method with i-Stat 1 - 365088 and Y Method i-Stat 2 - 365080 graph indicated slope of 1.383 and Corr Coef (R) 0.6366. c. The laboratory must demonstrate that it can obtain performance specifications comparable to those establish by the manufacture.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(4)(i)

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
 Based on review of the laboratory's proficiency testing (PT) test result reports, and interview with the laboratory testing personnel, it was determined that the laboratory director failed to ensure that the proficiency testing samples were tested as required to verify the accuracy of the testing system annually under Subpart H of 42 CFR part 493. The findings included: a. The laboratory used i-Stat instrument to perform Protime (Ptm) testing and enrolled with API (American Proficiency Institute) PT program to verify the accuracy of the testing system annually. b. The laboratory attained a score of 40% for Ptm testing in the 3rd 2019 PT events which was unsatisfactory analyte performance for the testing event, see D-2121

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
 Based on review of the laboratory's new instrument validation records, proficiency testing (PT) test result reports, and interview with the laboratory testing personnel, it

was determined that the laboratory director failed to ensure that the quality control programs was established and maintained to assure the quality of laboratory services provided. The findings included: a. This is an initial CLIA survey, the laboratory used i-Stat instrument to perform Protine (Ptm) testing. b. The laboratory performed verification of performance specifications and enrolled with API (American Proficiency Institute) PT program to verify the accuracy of the testing system annually. b. The laboratory failed to demonstrate and obtain its Ptm validation performance specifications comparable to those established by the manufacturer, see D-5421. c. The laboratory attained a score of 40% for Ptm testing in the 3rd 2019 PT events which was unsatisfactory Ptm performance for the 3rd 2019 PT testing event, see D-2121.