

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0554051	(X3) Date Survey Completed 01/15/2019
Name of Provider or Supplier Coast Hematology-Oncology	Street Address, City, State 701 E 28th St Ste 418, Long Beach, 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
D2122	<p>HEMATOLOGY CFR(s): 493.851(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on reviews of proficiency testing reports from CMS (report 155D, Individual Laboratory Profile) and AAB (American Association of Bioanalysts), laboratory proficiency testing documents, and patients tests records; and interview with Testing Person-1, the laboratory failed to attain an overall score of at least 80% for hematology testing using the Celdyn Emerald analyzer constituting unsatisfactory testing performance for 2017: event 2. Findings included: a. CMS and AAB reported the overall score of 55% based on the laboratory's unacceptable results and scores as follows: Analyte Acceptable results Score ----- RBC 0 out of 5 0% (Red Blood Cell Count) HCT (Hematocrit) 0 out of 5 0% Platelets 2 out of 5 40% b. Testing Person-1 affirmed (1/15/19) the aforementioned unacceptable results and unsatisfactory scores; and thus unsatisfactory testing performance. c. The accuracy, reliability, and quality of results reported could not be assured for the timeframe 6/01/17 - 10/22/17. Based on the reported estimated annual tests volumes, the laboratory reported approximately 284 results each month for RBC, HCT, and Platelets. Examples included: Date ID ----- 6/01/17 P, P 7/18/17 N, C 9/18/17 L, M</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification</p>

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 the Celldyn Emerald analyzer (serial number 034607000436), reviews of 2017-2018 laboratory documents for verifying calibrations, the lack of laboratory documents, and interview with Testing Person-1, the laboratory failed to perform and document procedures verifying instrument calibrations at least once every 6 months. Findings included: a. The Emerald was used to test for RBC, HCT, Hemoglobin (HGB), WBC (White Blood Cell Count), Differential, and Platelets. b. The manufacturer's Operator's Manual, section 6, Calibration, stated that criteria for Calibration verification included "At least every six months". c. Laboratory documents verifying instrument calibrations revealed procedures were performed on the following dates: 6/20/17 8/18/17 * 6/21/18 d. The laboratory failed to provide documents of procedures performed (*) within 6 months following 8/18/17. e. The Laboratory Director affirmed (memo, December 2018) and the Testing Person affirmed (1/15/19) that the documents for 6/21/18 exceeded 6 months from 8/18/17; thus constituting the laboratory's failure to verify instrument calibrations at least once every 6 months as required by the manufacturer. f. The reliability and quality of results reported could not be assured. Based on the reported estimated annual tests volumes, the laboratory reported approximately 2,646 results during the timeframe February 2018 to June 20, 2018.

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES
 CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:
 Based on the deficiency cited (D5439), the Technical Consultant (Laboratory Director) is herein cited for deficient practice in providing technical oversight of the laboratory. Findings included: a. The Technical Consultant (Laboratory Director) failed to ensure the laboratory adhered to manufacturer's requirements. See D5439.