

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D1083014	<b>(X3) Date Survey Completed</b>  04/23/2019
<b>Name of Provider or Supplier</b>  Central Coast Oncology & Hematology	<b>Street Address, City, State</b>  1669 Dominican Way, Santa Cruz, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2121</b>	<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 proficiency testing records for event 3, 2016, from CMS (Report 155D, Individual Laboratory Profile) and MLE (Medical Laboratory Evaluation), laboratory proficiency testing records, and patients test records; and interview with laboratory personnel, it was revealed that the laboratory failed to attain a score of at least 80% for Cell ID (microscopic blood cell identification). Findings included: a. CMS and MLE reported the unsatisfactory score of 60% based on 2 unacceptable results out of 5: PT sample.....Laboratory result (Intended result) ----- BC13...Neutrophil, segment /band with Toxic granules (Neutrophil; segmented or band) BC16...Monocyte (Lymphocyte, Reactive) b. Laboratory personnel affirmed (4/23/19 at 12:30pm) the aforementioned unsatisfactory score; and thus the laboratory's unsatisfactory performance in identifying types of blood cells. c. The reliability and quality of RBC, WBC, and Platelets results reported for blood smear reviews could not be assured. Based on laboratory personnel affirmation (4/23/19 at 12:30pm) that blood smears were examined approximately 2 - 3 times per week, the laboratory reported approximately 33 Peripheral Blood Smears during the timeframe November 2016 to January 2017. .</p>
<b>D2128</b>	<p>HEMATOLOGY CFR(s): 493.851(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training</p>

and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:

Based on the deficiency cited (D2121) and the lack of laboratory documents, it was determined that the laboratory failed to provide and document remedial activities for improvement, including appropriate additional training and technical assistance. Findings included: a. Review of proficiency testing records revealed the lack of documentation for remedial activities. See D2121.