

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0688544	<b>(X3) Date Survey Completed</b>  07/14/2021
<b>Name of Provider or Supplier</b>  Hematology/Oncology Consultants	<b>Street Address, City, State</b>  301 N San Jacinto St, Hemet, 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>D2123</b>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(c)</p> <p>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.</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 participate in a testing event is unsatisfactory performance. The findings included: a. The laboratory used Horiba ABX Micro 60 with 3-part WBC cell differentials to perform hematology and report the Complete Blood Cell Count (CBC) including WBC with 3-part differentials, RBC, Hemoglobin, Hematocrit, Platelet count. b. To ensure the accuracy of the patient test reports, the laboratory enroll with API (American Proficiency Institute) PT program. c. The laboratory failed to participate the first (Q1) 2021 hematology PT event. d. The laboratory performed CBC in approximately 500 patient samples monthly. e. The laboratory affirmed (7/15 /2021 @ 11:30 am) that the laboratory failed to participate the Q1 2021 PT event.</p>
<b>D6016</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(i)</p> <p>The laboratory director is responsible for the overall operation and administration of</p>

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. The findings included: a. The laboratory used Horiba ABX Micro 60 with 3-part WBC cell differentials to perform hematology and report the Complete Blood Cell Count (CBC) including WBC with 3-part differentials, RBC, Hemoglobin, Hematocrit, Platelet count. b. To ensure the accuracy of the patient test reports, the laboratory enroll with API (American Proficiency Institute) PT program. c. The laboratory failed to participate the first (Q1) 2021 hematology PT event and resulted in a score of 0 for this test event, see D-2123.