

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0930199	<b>(X3) Date Survey Completed</b>  02/12/2020
<b>Name of Provider or Supplier</b>  Merla Puray, Md	<b>Street Address, City, State</b>  3175 Collins Dr, Merced, 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 reviews of 2019 hematology proficiency testing reports from CMS (report 155D, Individual Laboratory Profile) and API (American Proficiency Institute), laboratory proficiency testing records, and ten (10) random patients results reviewed from 02/01/2018 to 01/16/2020, and an interview with laboratory personnel, it was revealed that the laboratory failed to participate in the 1st event of 2019. Findings included. a. CMS and API reported an unsatisfactory performance and results in a 0% for the first event (1Q), 2019 in hematology: WBC Differential RBC (Red Blood Cell count) HCT (Hematocrit) HGB (Hemoglobin) WBC (White Blood Cell count) Platelets (Platelets count) b. Laboratory proficiency records revealed the laboratory failed to participate in the event. c. Laboratory personnel confirmed (2/12/2020 at 11:45AM) the previously cited findings. d. Although the laboratory failed to participate in hematology proficiency testing, it continued testing and reporting results. The reliability and quality of hematology results could not be assured for the timeframe circumcising the 1st quarter proficiency event of 2019. e. The laboratory's testing declaration signed 02/12/220 estimated the annual volume of 7,375 hematology tests results reported.</p>

**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 reviews of the API (American Proficiency Institute) proficiency performance summary records, random patient sampling test results, and interview with the laboratory personnel, it was determined that the laboratory director failed to ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. See D 2123