

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0882434	(X3) Date Survey Completed 03/02/2021
Name of Provider or Supplier Medical Group Lancaster	Street Address, City, State 44469 10th St W, Lancaster, 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 review of the American Association of Bioanalysts (AAB) proficiency testing (PT) records and interview with the testing personnel (TP); it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent in Hematology Monocyte counts for the third event of 2019 (Q3-2019) which is unsatisfactory performance. The findings included: 1. On the date of the survey March 2, 2021 at approximately 11:00 a.m. based on review of the PT scores, the laboratory obtained for Hematology Monocyte automated count by Horiba ABX Micros Instrument for Q3-2019 and overall score of 40% as follow: Q3-2019 Monocyte Overall score 40%: Sample Reported Expected Score 11 4.7 5.0 - 9.9 U 12 33.3 10.7 - 36.5 A 13 10.8 4.8 - 10.1 U 14 4.6 1.9 - 4.5 U 15 33.6 11.1 - 35.8 A A = Acceptable U = Unacceptable 2. The TP affirmed on 03/02/2021 at approximately 12:00 pm the laboratory obtained the PT scores in 1. 3. According to the laboratory testing declaration submitted on the day of the survey (03/02/2021) for the years 2019-2020, the laboratory analyzed and reported approximately 3,650 (quarterly) WBC counts with differentials including Monocytes during the time the laboratory received an unsatisfactory PT performance score.</p>
D2127	<p>HEMATOLOGY CFR(s): 493.851(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p>

This STANDARD is not met as evidenced by:
Based on review of the American Association of Bioanalysts (AAB) proficiency testing reports and interview with the testing personnel (TP); it was determined that the laboratory failed to return proficiency testing results for Hematology for the second quarter event for 2020 (Q2-2020) to the proficiency testing program within the time frame specified by the program which is unsatisfactory performance and results in a score of zero (0). The findings included: 1. The AAB proficiency agency reported to CMS for Q2-2020 an unsatisfactory score of 0% for Cell ID or WBC Diff, RBC, HCT (non-waived), Hemoglobin (non-waived), WBC, and platelets failure to submit results within the time frame specified by the program. 2. The TP affirmed on March 2, 2021 at approximately 11:30 a.m. that the AAB Hematology proficiency score for Q-2 2020 of zero (0%) was obtained. 3. Based on the laboratory's annual test volume declaration on 03/02/2021 the laboratory analyzed and reported approximately 3,650 Hematology tests during the time the PT results were unsatisfactory.

D6017

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

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)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:
Based on review of the second quarter of 2020 of the American Association of Bioanalysts proficiency testing records, random patient test results, and interview with the testing person, it was determined that the laboratory director failed to ensure that results are returned within the timeframes established by the proficiency testing program. See D 2127.