

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2078669	(X3) Date Survey Completed 04/29/2021
Name of Provider or Supplier Legacy Md Medical Group Inc	Street Address, City, State 222 E Cole Blvd, Calexico, 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
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(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 interviews with the staff on April 29, 2021, review of CMS 155 report (Individual Laboratory Profile) and review of American Proficiency Institute (customer number 73669) proficiency testing records from the 1st testing event of 2019 through the 1st testing event of 2021, for one out of seven proficiency testing events reviewed, the laboratory failed to attain a score of at least 80 percent in total cholesterol testing. The findings included: a. The laboratory performs total cholesterol testing on the Horiba ABX Pentra 400 analyzer. b. Laboratory proficiency testing records as well as the CMS 155 Report showed the laboratory attained a score of 20% for total cholesterol testing during the 3rd proficiency testing event of 2019. c. A testing person affirmed on April 29, 2021 at approximately 11:00 am, the unsatisfactory score of 20% obtained by the laboratory for total cholesterol testing during the 3rd proficiency testing event of 2019. d. Based on the annual test volume reported, the laboratory performed and reported approximately 100,000 tests under the specialty of chemistry.</p>
D2121	<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:</p>

Based on interviews with the staff on April 29, 2021, review of CMS 155 report (Individual Laboratory Profile) and review of American Proficiency Institute (customer number 73669) proficiency testing records from the 1st testing event of 2019 through the 1st testing event of 2021, the laboratory failed to attain a score of at least 80 percent in white blood cell (WBC) differential (lymphocyte, granulocyte, and monocyte identification) testing. The findings included: a. The laboratory performs complete blood count (CBC) testing on the Horiba ABX Micros 60 analyzer (serial number: S12C595452). b. Laboratory proficiency testing records as well as the CMS 155 Report showed the laboratory attained the following scores for each individual analyte. 1. Proficiency testing results in white blood cell (WBC) differential (lymphocyte, granulocyte, and monocyte identification) failed to attain an overall testing score of 80 percent for the 1st event of 2019. a) Granulocyte count proficiency test results indicated that four out of five American Proficiency Institute proficiency samples tested were not within acceptable range. Sample Reported Expected Performance HEM-01 62.9 64.4 - 70.1 Unacceptable HEM-02 36.1 35.8 - 43.1 Acceptable HEM-03 77.0 77.5 - 83.1 Unacceptable HEM-04 61.9 62.6 - 67.9 Unacceptable HEM-05 69.2 72.8 - 82.6 Unacceptable A testing person affirmed on April 29, 2021 at approximately 11:00 am, the unsatisfactory score of 20% obtained by the laboratory for granulocyte count testing during the 1st proficiency testing event of 2019. b) Lymphocyte count proficiency test results indicated that two out of five American Proficiency Institute proficiency samples tested were not within acceptable range. Sample Reported Expected Performance HEM-01 30.2 24.6 - 29.9 Unacceptable HEM-02 59.8 46.5 - 59.3 Unacceptable HEM-03 16.4 13.8 - 17.3 Acceptable HEM-04 32.4 26.0 - 32.6 Acceptable HEM-05 17.7 4.0 - 18.0 Acceptable A testing person affirmed on April 29, 2021 at approximately 11:00 am, the unsatisfactory score of 60% obtained by the laboratory for lymphocyte count testing during the 1st proficiency testing event of 2019. c) Monocyte count proficiency test results indicated that two out of five American Proficiency Institute proficiency samples tested were not within acceptable range. Sample Reported Expected Performance HEM-01 6.9 3.4 - 7.7 Acceptable HEM-02 4.1 2.7 - 12.6 Acceptable HEM-03 6.6 2.3 - 6.1 Unacceptable HEM-04 5.7 3.1 - 7.7 Acceptable HEM-05 13.1 2.9 - 9.4 Unacceptable A testing person affirmed on April 29, 2021 at approximately 11:00 am, the unsatisfactory score of 60% obtained by the laboratory for monocyte count testing during the 1st proficiency testing event of 2019. 2. Proficiency testing results in white blood cell (WBC) differential (lymphocyte, granulocyte, and monocyte identification) failed to attain an overall testing score of 80 percent for the 1st event of 2020. a) Granulocyte count proficiency test results indicated that four out of five American Proficiency Institute proficiency samples tested were not within acceptable range. Sample Reported Expected Performance HEM-01 36.3 32.9 - 39.6 Acceptable HEM-02 77.4 78.0 - 82.6 Unacceptable HEM-03 63.2 63.4 - 68.0 Unacceptable HEM-04 62.1 62.2 - 67.0 Unacceptable HEM-05 73.2 75.2 - 83.7 Unacceptable A testing person affirmed on April 29, 2021 at approximately 11:00 am, the unsatisfactory score of 20% obtained by the laboratory for granulocyte count testing during the 1st proficiency testing event of 2020. b) Lymphocyte count proficiency test results indicated that two out of five American Proficiency Institute proficiency samples tested were not within acceptable range. Sample Reported Expected Performance HEM-01 56.5 42.1 - 59.4 Acceptable HEM-02 17.1 12.7 - 17.0 Unacceptable HEM-03 31.5 23.4 - 31.3 Unacceptable HEM-04 32.2 23.4 - 32.2 Acceptable HEM-05 16.1 13.4 - 17.1 Acceptable A testing person affirmed on April 29, 2021 at approximately 11:00 am, the unsatisfactory score of 60% obtained by the laboratory for lymphocyte count testing during the 1st proficiency testing event of 2020. c. Based on the annual test volume reported, the laboratory performed and reported approximately 45,000 tests for the specialty of hematology.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

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)(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 interview with staff and review of quality control records, the laboratory director failed to ensure the proficiency samples are tested as required under Subpart H of this part. The findings included: a. The laboratory failed to attain satisfactory analyte performance for proficiency testing in the specialties of chemistry (refer to D2087) and hematology (refer to D2121).