

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0887027	(X3) Date Survey Completed 06/22/2021
Name of Provider or Supplier Antonio M Garcia, Md	Street Address, City, State 586 E Mission Blvd, Pomona, 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
D2128	<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 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.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the proficiency testing records, lack of laboratory documentation, and interview with the testing personnel (TP); it was determined that the laboratory failed to provide documentation for remedial actions taken for improvement of proficiency testing performance, including appropriate additional training and technical assistance. Findings included: 1. Review of proficiency testing records revealed the lack of documentation for remedial activities. 2. The TP confirmed the lack of documentation of corrective actions reports for proficiency testing unacceptable results.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on the lack of documentation and interview with the testing personnel (TP) on June 22, 2021, as specified in the personnel requirements in subpart M, the laboratory failed to establish and follow written policies and procedures to assess all testing personnel competency. Findings include: 1. The laboratory had four (4) testing personnel (TP). 2. Two (2) out of four (4) of the TP processing samples and performing testing did not have any documentation of training or competency for the tests performed at the laboratory. 3. This deficient practice was affirmed by interview with the TP on June 23, 2021 at approximately 12:10 p.m. 4. The laboratory reportedly performs approximately 1,020 tests annually.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
Based on the surveyors' observation, examination of laboratory reagents, and interview with the testing personnel (TP), it was determined that the laboratory failed to not use reagents when they have exceeded their expiration date. The findings included: 1. On the day of inspection, June 22, 2021 at approximately 11:00 a.m., the surveyor found the following vacutainer tubes being used beyond its expiration date: Vacutainer Lot number Expiration date K2 EDTA 9095746 09/31/2020 Na Citrate 9065707 12/31/2019 K2 EDTA 0072556 03/31/2021 Lithium 366667 12/31/2020 K2 EDTA 9260548 01/21/23021 Red Top 9123785 04/30/2021 Na Citrate 0133231 02/28 /2021 2. The TP affirmed on 06/22/2021 at approximately 11:10 a.m. using the vacutainers tubes listed in (1) beyond its expiration date. 3. Based on the laboratory's submitted testing declaration volume, the laboratory tests and reports approximately 1,020 tests annually.

D5433

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:
Based on the surveyor's observation, lack of maintenance protocol and documentation, and interview with the laboratory's testing personnel (TP); it was determined that the laboratory failed to establish and document a maintenance protocol for the Hematology analyzer that ensures its continued performance necessary for accurate and reliable test results. The findings included: 1. The laboratory uses the Horiba ABX Micro MES 60 Analyzer for Hematology blood testing in the laboratory. 2. Based on surveyor observation during tour of the laboratory on June 22, 2021 at approximately 11:30 a.m. the equipment described

above used in the laboratory had no records of maintenance for the month of March 2021. 3. The TP affirmed that the laboratory failed to establish a maintenance protocol for the Hematology analyzer described in 1. 4. Based on the laboratory's monthly testing declaration submitted at the time of the survey, the laboratory analyzed and reported approximately 1,020 hematology samples annually.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on review and the lack of documentation for competency assessments and interview with the testing personnel; for two (2) out of four (4) testing personnel (TP) records reviewed for the years 2019 and 2020, it was determined that the laboratory's technical consultant failed to perform and document the performance of individuals responsible for moderate complexity testing annually the individual tests patient specimens. (See D5209).