

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0925718	(X3) Date Survey Completed 03/26/2019
Name of Provider or Supplier Los Angeles Hematology	Street Address, City, State 2080 Century Park East #1005, Los Angeles, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by:</p> <p>1. Based on interview with the Technical Consultant on 03/26/19, review of the laboratory's proficiency testing records from the 1st testing event of 2017 through the 3rd proficiency proficiency testing event of 2018, it was determined that the laboratory failed to verify the accuracy of its Free Testosterone assay, at least twice a year. The findings included: a. In 2017 and 2018, the laboratory had elected to enroll in proficiency testing as its means of verifying the accuracy of the Immulite 2000 (SN# J4129) Free Testosterone assay performed, which is not included under subpart I of this part of CLIA. b. A review of the performance summary report provided to the laboratory by its proficiency testing provider, American Proficiency Institute (API), showed the laboratory obtained unsatisfactory scores for the 1st proficiency testing events of 2017 and 2018, constituting failure to verify the accuracy of the Free Testosterone, at least twice a year. Testing Event Analyte Score Q1 2017 Free Testosterone 0% Q1 2018 Free Testosterone 67% c. The laboratory tested and reported Free Testosterone results for the following five patient samples: Date tested Accession #s 03/08/2018 96348 03/26/2018 96786 04/04/2018 97108 05/08/2018 98128 09/20/2018 101617 d. The laboratory staff affirmed (03/2 6/20 19 at approximately 11:00 a.m.) the laboratory failed to verify the accuracy of its Free Testosterone assay, at least twice a year. 2. Based on interview with the Technical Consultant on 03/26/19, review of the laboratory's proficiency testing records from the 1st testing event of 2017 through the 3rd proficiency proficiency testing event of 2018, it was determined that the laboratory failed to verify the accuracy of its Parathyroid Hormone (PTH) assay, at least twice a year. The findings included: a. In 2017 and 2018, the laboratory had elected to enroll in proficiency testing as its means</p>

of verifying the accuracy of the Immulite 2000 (SN# J4129) PTH performed, which is not included under subpart I of this part of CLIA. b. A review of the performance summary report provided to the laboratory by its proficiency testing provider, American Proficiency Institute (API), showed the laboratory obtained unsatisfactory scores for the 1st proficiency testing event of 2017 and 2nd proficiency testing event of 2018, constituting failure to verify the accuracy of the PTH, at least twice a year. Testing Event Analyte Score Q1 2017 PTH 67% Q2 2017 PTH 33% c. The laboratory tested and reported PTH results for the following six patient samples: Date tested Accession #s 04/10/2018 97241 04/17/2018 97452 04/23/2018 97655 05/01/2018 97886 05/08/2018 198128 05/10/2018 98212 d. The laboratory staff affirmed (03/26/2019 at approximately 11:30 a.m.) the laboratory failed to verify the accuracy of its PTH assay, at least twice a year. 3. Based on interview with the technical consultant on 03/26/19, review of the laboratory's proficiency testing records from the 1st testing event of 2017 through the 3rd proficiency testing event of 2018, it was determined that the laboratory failed to verify the accuracy of its Erythrocyte Sedimentation Rate (ESR) assay, at least twice a year. The findings included: a. In 2017 and 2018, the laboratory had elected to enroll in proficiency testing as its means of verifying the accuracy of the Dispette3 ESR assay performed, which is not included under subpart I of this part of CLIA. b. A review of the performance summary report provided to the laboratory by its proficiency testing provider, American Proficiency Institute (API), showed the laboratory obtained unsatisfactory scores for the 2nd and 3rd proficiency testing events of 2017, constituting failure to verify the accuracy of the ESR, at least twice a year. Testing Event Analyte Score Q2 2017 ESR 50% Q3 2017 ESR 50% c. The laboratory tested and reported ESR results for the following nine patient samples: Date tested Accession #s 07/12/2017 88985 07/12/2017 88987 07/12/2017 88989 07/12/2017 88997 07/12/2017 89002 07/12/2017 88991 07/12/2017 88994 11/16/2017 92753 11/16/2017 92759 d. The laboratory staff affirmed (03/26/2019 at approximately 1:00 p.m.) the laboratory failed to verify the accuracy of its ESR assay, at least twice a year. .

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 of laboratory personnel reports (CMS209, LAB116) and documents for annual competency assessment, the lack of laboratory documents, and interview with laboratory personnel, the Technical Consultant failed to evaluate the performance of Testing Person for Erythrocyte Sedimentation Rate (ESR) at least semiannually during the first year of testing, and annually thereafter . Findings included: a. Documents for 2018 annual competency assessment were provided for the testing person named on the laboratory personnel reports. b. The laboratory failed to provide document(s) for competency assessment for the testing person performing ESR utilizing Dispette3 at least semiannually during the first year, and annually thereafter. c. The reliability and quality of results reported could not be assured when competency was not assessed and documented at least semiannually during the first year of testing, and annually thereafter. Examples of ESR testing performed by Testing Person in 2017 are as follows: Date tested Accession #s 07/12/2017 88985 07/12/2017 88987 07/12/2017 88989 07/12/2017 88997 07/12/2017 89002 07/12/2017

88991 07/12/2017 88994 11/16/2017 92753 11/16/2017 92759 d. The laboratory person affirmed (03/26/19 at approximately 1:00 p.m.) the lack of aforementioned semiannual competency assessment for the testing person performing ESR and thus, the failure of the Technical Consultant to evaluate and document testing performance at least semiannually during the first year, and annually thereafter.