

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0925718	(X3) Date Survey Completed 11/10/2021
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
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 Surveyor review of laboratory's proficiency testing (PT) result evaluation from American Proficiency Institute (API) and interview with the laboratory technical consultant on November 10, 2021 at 12:34 pm, the laboratory failed to attain a score of at least 80 percent of acceptable responses for Chloride, Potassium and Sodium at the 1st event of 2021. The findings include: 1. The laboratory performed Chloride, Potassium and Sodium testing using an automated ACE Axcel instrument. To verify its test accuracy, the laboratory participated in API PT testing for the year of 2021. However, it received a score of 60% and 40% for Chloride and Potassium/Sodium, respectively at the 1st event resulting in an unsatisfactory analyte performance for the event. Therefore, the failure in the PT event suggesting that the patients' Chloride, Potassium and Sodium results reported during the PT event period might had not been accurate and thus causing patient harm. 2. The laboratory technical consultant on November 10, 2021 at 12:34 pm, affirmed that the laboratory had received a score of 60% and 40% for Chloride and Potassium/Sodium, respectively at the 1st event. 3. The laboratory's testing declaration form, signed by the laboratory Director on 11/10 /2021, stated that the laboratory performs approximately 2,820 (each) Chloride, Potassium and Sodium tests, annually.</p>
D2094	<p>ROUTINE CHEMISTRY CFR(s): 493.841(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</p>

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.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's proficiency testing (PT) results from American Proficiency Institute (API), remedial action documentation and interview with the laboratory technical consultant on November 10, 2021 at 12:34 pm, the laboratory failed to take an appropriate remedial action after obtaining an unsatisfactory analyte performance for Chloride, Potassium and Sodium at the 1st event of 2021. The findings include: 1. The laboratory performed Chloride, Potassium and Sodium testing using an automated ACE Axcel instrument. To verify its test accuracy, the laboratory participated in API PT testing for the year of 2021, and obtained an unsatisfactory analyte performance at the 1st event for Chloride, Potassium and Sodium. Therefore, the failure in the PT event suggesting that the patients' Chloride, Potassium and Sodium results reported during the PT event period might had not been accurate and thus causing patient harm. However, the laboratory did not investigate any effect on patient care during that PT period. 2. The laboratory technical consultant on November 10, 2021 at 12:34 pm, affirmed that the laboratory's remedial action plan was not available. 3. The laboratory's testing declaration form, signed by the laboratory Director on 11/10/2021, stated that the laboratory performs approximately 2,820 (each) Chloride, Potassium and Sodium tests, annually.

D5783

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's quality control (QC) records, lack of corrective actions documentations and interview with the laboratory technical consultant on November 10, 2021 at 11:35 am, the laboratory failed to take any corrective actions when MG and LDL QC values were outside of acceptable range on 11/05/2021. The findings include: 1. The laboratory's MG and LDL QC results were outside of acceptable ranges on 11/05/2021. However, the laboratory did not take or document any corrective actions. Therefore, the accuracy of the MG and LDL results reported to the patient could not be assured and thus might have caused patient harm. 2. The laboratory technical consultant on November 10, 2021 at 11:35 am, affirmed that the laboratory did not document the corrective actions taken. 3. The laboratory's testing declaration form, signed by the laboratory Director on 11/10/2021, stated that the laboratory performs 1,173 MG tests, annually.

D6004

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's policy & procedure, quality control (QC) records, proficiency testing (PT) results from American Proficiency Institute (API), lack of remedial and corrective actions documentation and interview with the laboratory technical consultant on November 10, 2021 at 12:34 pm, the laboratory director failed to ensure compliance with the applicable regulations. The findings include: See D2087, D2094 and D5783.

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 Surveyor review of laboratory's policy & procedure, proficiency testing (PT) results from American Proficiency Institute (API), lack of remedial action records and interview with the laboratory technical consultant on November 10, 2021 at 12:34 pm, the laboratory director failed to ensure that an approved corrective action plan is followed when the PT results of Chloride, Potassium and Sodium at the 1st event of 2021 are found to be unacceptable or unsatisfactory. Findings include: The laboratory did not follow an approved corrective action plan after receiving unacceptable PT evaluations from API for Chloride, Potassium and Sodium at the 1st event of 2021. See D2094.

D6023

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(6)

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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's proficiency testing (PT) results from American Proficiency Institute (API) and interview with the laboratory technical consultant on November 10, 2021 at 12:34 pm, the laboratory failed to attain a score of at least 80 percent of acceptable responses for Chloride, Potassium and Sodium at the 1st event of 2021 and received an unsatisfactory analyte performance evaluation for the testing event. The findings include: See D2087.

D6075

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1425(b)(6)

Each individual performing moderate complexity testing must document all corrective actions taken when test systems deviate from the laboratory's established performance specifications.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's quality control (QC) records, lack of corrective actions documentations and interview with the laboratory technical consultant on November 10, 2021 at 11:35 am, the laboratory testing person #1 failed to take any corrective actions when MG and LDL QC values were outside of acceptable range on 11/05/2021. The findings include: 1. The laboratory's MG and LDL QC results were outside of acceptable ranges on 11/05/2021. However, the laboratory testing person #1 did not take or document any corrective actions. Therefore, the accuracy of the MG and LDL results reported to the patient could not be assured and thus might have caused patient harm. 2. The laboratory technical consultant on November 10, 2021 at 11:35 am, affirmed that the testing person #1 did not document the corrective actions taken. 3. The laboratory's testing declaration form, signed by the laboratory Director on 11/10/2021, stated that the laboratory performs 1,173 MG tests, annually.