

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0692916	(X3) Date Survey Completed 10/12/2021
Name of Provider or Supplier Lab-All Inc	Street Address, City, State 2200 W 7th St Ste 305, 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) evaluation reports from American Association of Bioanalysts (AAB), and interview with the laboratory testing person #1 on October 12, 2021 at 10:45 am, the laboratory failed to attain a score of at least 80 percent of acceptable responses for the analyte Iron at the 1st event (Q1) of 2020 resulting in an unsatisfactory analyte performance for the testing event. The unsatisfactory PT performance suggesting that the laboratory might have reported inaccurate test results for the analyte Iron to the patient during the PT event and thus had harmed patients. The findings include: 1. The laboratory enrolled in the PT program with AAB for assessing laboratory's performance and verifying the accuracy and reliability of its test results, however it received an unsatisfactory performance for the analyte Iron at the 1st event of 2020. The laboratory received a score of 40 % for Iron at the Q1 2020 PT event, which was unsatisfactory analyte performance. Q1 2020 Iron result accepted range Specimen 1 48 27 to 40 Specimen 4 230 120 to 180 Specimen 5 346 182 to 272 Overall score: 40% Unacceptable 2. The laboratory testing person #1, on October 12, 2021 at 10:45 am, affirmed that the laboratory received a score of 40% for Iron at the Q1 2020 PT event. 3. Based on the laboratory's annual test volume declaration form signed by the laboratory director, the laboratory analyzed and reported approximately 542 Iron 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</p>

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.

This STANDARD is not met as evidenced by:

Based on review of American Association of Bioanalysts (AAB) proficiency testing records, lack of laboratory's remedial action records, and interview with the testing person #1 on October 12, 2021 at 10:50 am, it was determined that the laboratory failed to take any remedial action to correct problems after receiving an unsatisfactory proficiency testing (PT) performance for the analyte Iron at the 1st event of 2020. The findings include: 1. The laboratory received an unsatisfactory score (40%) for the analyte Iron at the 1st PT event of 2020 PT. See D2087. However, it did not take any remedial action to correct the PT failure and continued to test patient causing inaccurate test results which might have harmed patients. 2. The laboratory testing person #1, on October 12, 2021 at 10:50 am, affirmed that the laboratory did not take any remedial action for the Iron PT failure and thus did not have any documentation. However, it had documentation of remedial action taken for the PT failure of some other analytes including Potassium. 3. Based on the laboratory's annual test volume declaration form signed by the laboratory director, the laboratory analyzed and reported approximately 542 Iron tests, annually. .

D2122

HEMATOLOGY

CFR(s): 493.851(b)

Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's proficiency testing (PT) evaluation reports from American Association of Bioanalysts (AAB), and interview with the laboratory testing person #1 on October 12, 2021 at 11:15 am, the laboratory failed to attain a score of at least 80 percent of acceptable responses for the Hematology analytes WBC, RBC, Hemoglobin, Hematocrit and Platelets at the 2nd event (Q2) of 2021 resulting in an unsatisfactory analyte performance for the testing event. The unsatisfactory PT performance suggesting that the laboratory might have reported inaccurate test results for the above analytes to the patient during the PT event and thus had harmed patients. The findings include: 1. The laboratory received the following unsatisfactory PT scores for WBC, RBC, Hemoglobin, Hematocrit and Platelets at the 2nd event (Q2) of 2021: WBC Overall score 60% Sample Reported Expected Score 1 7.3 7.9 - 10.7 U 4 9.5 6.1 - 8.2 U RBC Overall score 60% Sample Reported Expected Score 1 4.69 5.83 - 6.57 U 4 6.25 4.29 - 4.84 U Hemoglobin Overall score 60% Sample Reported Expected Score 1 13.4 17.1 - 19.7 U 4 8.4 12.5 - 14.4 U Hematocrit Overall score 60% Sample Reported Expected Score 1 39.2 49.1-55.4 U 4 52.4 36.1 - 40.8 U Platelet Overall score 60% Sample Reported Expected Score 1 239 63 -105 U 4 77 180-299 U 2. The laboratory testing person #1, on October 12, 2021 at 11:15 am, affirmed that the laboratory received an unsuccessful PT score of 60% for WBC, RBC, Hemoglobin, Hematocrit and Platelets at the 2nd event (Q2) of 2021. 3. According to the laboratory testing declaration form signed by

the laboratory director, the laboratory performed approximately 9,000 Hematology tests, quarterly. .

D2128

HEMATOLOGY
CFR(s): 493.851(e)

(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.

This STANDARD is not met as evidenced by:
Based on Surveyor review of American Association of Bioanalysts (AAB) proficiency testing records, lack of laboratory's remedial action records, and interview with the testing person #1 on October 12, 2021 at 11:20 am, it was determined that the laboratory failed to take any remedial action to correct problems after receiving an unsatisfactory proficiency testing (PT) performance for the Hematology analytes WBC, RBC, Hemoglobin, Hematocrit and Platelets at the 2nd event (Q2) of 2021. The findings include: 1. The laboratory received an unsatisfactory score (60%) for the Hematology analytes WBC, RBC, Hemoglobin, Hematocrit and Platelets at the 2nd PT event (Q2) of 2021. See D2122. However, it did not take any remedial action to correct the PT failure and continued to test patient causing inaccurate test results which might had harmed patients. 2. The laboratory testing person #1, on October 12, 2021 at 11:20 am, affirmed that the laboratory did not take any remedial action for the failed PT event and thus did not have any documentation. 3. According to the laboratory testing declaration form signed by the laboratory director, the laboratory performed approximately 9,000 Hematology tests, quarterly. .

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

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.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's proficiency testing (PT) evaluation reports from American Association of Bioanalysts (AAB), test verification records, and interview with the laboratory testing person #1 on October 12, 2021 at 12:15 pm, the laboratory failed to verify the accuracy of Folate in 2019 and 2020, and Testosterone in 2020. The laboratory's failure in the verification of test accuracy suggesting that the laboratory might have reported inaccurate test results for the analytes Folate and Testosterone to the patient during the PT event and thus had harmed patients. The findings include: 1. The laboratory had participated in the AAB PT program in 2019 and 2020 to verify the accuracy of Folate and Testosterone tests. However, the verification was unsuccessful. a) During review of laboratory documentation from AAB, there were 3 consecutive events where folate was tested unsuccessfully. The laboratory received the following AAB scores for Folate: Q3 2019 Folate overall result 0% Q1 2020 Folate overall result 50% Q2 2020 Folate overall result 50% b)

The laboratory received a score of 50% for Testosterone at the Q1 2020 PT event, which was unsatisfactory analyte performance. Q1 2020 Testosterone result accepted range Specimen 1 49 88 to 164 Overall score 50% Unacceptable c) The laboratory did not verify the Folate and Testosterone test accuracy by any other method. 2. The laboratory testing person #1, on October 12, 2021 at 12:15 pm, affirmed that the laboratory was unsuccessful in verifying the Folate and Testosterone test accuracy in 2019 and 2020. 3. According to the laboratory testing declaration form signed by the laboratory director, the laboratory performed approximately 77 Testosterone and 542 Folate tests, annually. .

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's policies and procedures, proficiency testing (PT) evaluation reports from American Association of Bioanalysts (AAB), and interview with the laboratory testing person #1 on October 12, 2021 at 12:45 pm, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems associated with the evaluation of proficiency testing performance and verification of test accuracy. The findings include: 1. The laboratory failed to verify the accuracy of Folate and Testosterone tests and lacked in the evaluation of proficiency testing results. See D2094, D2128 and D5217. However, laboratory's quality assessment program was not sufficient to find and correct the problems in the general laboratory system. 2. The laboratory testing person #1, on October 12, 2021 at 12:45 pm, affirmed that the laboratory did not have an ongoing mechanism to identify and correct problems associated with the general laboratory system. 3. Based on the laboratory's annual test volume declaration form signed by the laboratory director, the laboratory analyzed and reported approximately 529 Folate and 77 Testosterone 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 and interview with the laboratory testing person #1 on October 12, 2021 at 12:50 pm, the laboratory failed to follow its written policy when the QC results did not meet the laboratory's

established criteria of acceptability for 3 tests out of 5 tests reviewed. The findings include: 1) Laboratory's procedure stated rejection of control if QC results violates "10T rejection rule (Required)". At the review of QC Levy-Jennings chart for July, 2021, surveyor found that the results of QC for Alk Phos, HDL and Cholesterol failed to meet the laboratory's established criteria for acceptability. All QC results were violated the laboratory's established 10T rejection rule, but the laboratory did not take any action to correct the QC problem. Laboratory's failure to correct the QC problem on time might have negatively affected the patients test results causing harm. 2) The laboratory testing person #1, on October 12, 2021 at 12:50 pm, affirmed that the laboratory did not follow its established procedure to resolve the QC problems. 3) Laboratory's test volume declaration form stated a total annual volume of 4,027 Alk. Phos., 2,599 HDL and 4,222 Cholesterol tests had been performed on patients' samples. .

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 American Association of Bioanalysts (AAB) proficiency testing records, lack of laboratory's remedial action records, and interview with the testing person #1 on October 12, 2021 at 11:20 am, the laboratory director failed to ensure that an approved corrective action plan is followed when the proficiency testing results of Iron, WBC, RBC, Hemoglobin, Hematocrit and Platelets are found to be unacceptable or unsatisfactory. Findings include: The laboratory did not take any corrective actions after receiving unacceptable Proficiency testing evaluations from AAB for Iron, WBC, RBC, Hemoglobin, Hematocrit and Platelets. See D2087, D2094, D2122 and D2128. .

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's policies and procedures, proficiency testing (PT) evaluation reports from American Association of Bioanalysts (AAB), and interview with the laboratory testing person #1 on October 12, 2021 at 12:45 pm, the

laboratory director failed to ensure that the quality assessment programs are established and maintained to identify and correct the problems in the general laboratory systems. See D85291. .

D6024

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(7)

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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,

This STANDARD is not met as evidenced by:

Based on Surveyor review of American Association of Bioanalysts (AAB) proficiency testing records, lack of laboratory's remedial action records, and interview with the testing person #1 on October 12, 2021 at 11:20 am, it was determined that the laboratory director failed to ensure that all necessary remedial actions were taken and documented when the laboratory failed to receive a satisfactory test performance from the proficiency testing organization and failed to verify its test accuracy. See D2094, D2128 and D5217. .

D6042

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's quality control (QC) records and interview with the laboratory testing person #1 on October 12, 2021 at 12:50 pm, the laboratory technical consultant failed to ensure that the laboratory maintained an acceptable level of analytical performance when the QC results of Alk. Phos., HDL and Cholesterol tests did not meet the laboratory's established criteria of acceptability. See D5783.