Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0553321	04/22/2024
Name of Provider or Supplier	**Street Address, City, State**	
Los Alamitos Hematology/Oncology	3801 Katella Ave Ste 207, Los Alamitos, 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
D2121	HEMATOLOGY CFR(s): 493.851(a) 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. This STANDARD is not met as evidenced by: Based on surveyor review of the API proficiency testing evaluation report for the third event of 2022 and interview with the laboratory staff on 04/22/2024 at 11:30 AM, the laboratory failed to attain a score of at least 80 percent for monocytes for the 3rd event of 2022. The findings include: 1) The laboratory performed Complete Blood Count (CBC) test using HORIBA ABX Micros 60 Analyzer. The laboratory participated in the American Proficiency Institute (API) proficiency testing program for the CBC test in 2022, 2023 and 2024. The laboratory attained a score of 40 percent for monocytes for the 3rd event of 2022, which was unsatisfactory for the testing event. Therefore, the accuracy of the laboratory's test results cannot be assured and may have potential to harm patients. 2) On 04/22/2024 at 11:30 AM, the laboratory testing personnel confirmed that the laboratory attained a score of 40 percent for monocytes and the laboratory director signed the proficiency testing performance evaluation form. 3) The laboratory's testing declaration form, signed by the laboratory director on 04/19/2024 stated that the laboratory performed approximately 8,000 tests in hematology, annually.
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 the API proficiency testing evaluation report for the first and third events of 2022 and interview with the laboratory staff on 04/22/2024 at 11: 30 AM, the laboratory failed to take remedial action for the unacceptable results of Monocytes and Leukocytes in the first and third events of 2022, respectively. The findings include: 1) The laboratory performed Complete Blood Count (CBC) test using HORIBA ABX Micros 60 automated analyzer. The laboratory participated in the American Proficiency Institute (API) proficiency testing program for the CBC test in 2022, 2023 and 2024. In 2022, the laboratory had one unacceptable result for monocytes out of 5 samples during the first event and one unacceptable result for leukocytes count out of 5 samples during the third event. The laboratory failed to take remedial action for the unacceptable results for monocytes and leukocytes. Therefore, the accuracy of the laboratory's test results cannot be assured and may have potential to harm patients. 2) On 04/22/2024 at 11:30 AM, the laboratory testing personnel confirmed that the laboratory did not take remedial action for unacceptable hematology results. 3)The laboratory's testing declaration form, signed by the laboratory director on 04/19/2024 stated that the laboratory performed approximately 8,000 tests in hematology, annually.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory's personnel competency evaluation policy and documents, and interview with the laboratory staff on 04/22/2024 at 11:30 AM, the laboratory failed to have and follow written policies and procedures to assess employee. The findings include: 1) The laboratory did not have a written policy and procedure to assess employee. The laboratory did not perform competency assessment of any of the 3 testing personnel in 2023 and 2024. The last competency evaluation for the testing personnel were performed on 01/28/2022. Therefore, the competency of the testing personnel cannot be assured and may have potential to harm patients as incompetent personnel might report incorrect results. 2) On 04/22/2024 at 11:30 AM, the laboratory testing personnel confirmed the laboratory did not have policy and procedure for personnel competency training and all three testing personnels did not have a competency evaluation in 2023 and 2024. 3) The laboratory's testing declaration form, signed by the laboratory director on 04/19/2024 stated that the laboratory performed approximately 8,000 tests in hematology, annually.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The

	laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Levy-Jennings graphs and interview with the laboratory staff on 04/22/2024 at 11:30 AM, the laboratory failed to monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. The findings include: 1) The laboratory did not monitor over time the accuracy and precision of test performance. From 07/03/2023 to 07/31/2023, there was a shift in the Levy-Jennings graph for platelet counts, MCV and RBC, and from 03/02/2023 to 05/05/2023, there was a shift for RBC, HGB, HCT and the laboratory did not monitor them and failed to take action to correct the problems. Therefore, the accuracy of the laboratory's test result cannot be assured and might have had harmed patient. 2) On 04/22/2024 at 11:30 AM, the laboratory testing personnel confirmed the laboratory did not review the Levy-Jennings graphs to monitor the trend and shift. 3) The laboratory's testing declaration form, signed by the laboratory director on 04/19 /2024 stated that the laboratory performed approximately 8000 tests in hematology, annually.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory's hematology automated analyzer testing records and interview with the testing personnel on 04/22/2024 at 11:30 AM, the laboratory failed to have and follow corrective action policy and procedure as necessary for testing and reporting patient specimens that ensures accurate and reliable patient test results and reports. The findings include: 1) The laboratory did not have a corrective action policy and procedure for the CBC test to resolve the issue when the hematology analyzer generates a (!) flag next to CBC parameter. On 04/22 /2024, the analyzer generated a (!) flag for Lymphocyte, monocyte, eosinophile and basophile for sample ID #197257. The test results with flagged values were reported for the patient without any corrective action. Therefore, the accuracy and reliability of the laboratory's test result cannot be assured and might have had harmed patient. 2) On 04/22/2024 at 11:30 AM, the laboratory testing personnel confirmed that the laboratory reported analyte results with (!) flag and did not have any corrective action policy and procedure for hematology analyzer when the analyzer generates a (!) flag. 3) The laboratory's testing declaration form, signed by the laboratory director on 04/19 /2024 stated that the laboratory performed approximately 8,000 CBC tests in hematology, annually.

D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on surveyor review of the API proficiency testing evaluation report and interview with the laboratory staff on 04/22/2024 at 11:30AM, the laboratory director failed to provide effective direction to identify the problems that requires corrective action for the unacceptable results in the first and third events of 2022. The findings include: See D2128.
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on surveyor review of the Levy-Jennings graphs and interview with the laboratory staff on 04/22/2024 at 11:30 AM, the laboratory director failed to ensure that quality control programs are established and maintained to assure the quality of laboratory services. The findings include: See D5441
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 the hematology automated analyzer testing records and interview with the testing personnel on 04/22/2024 at 11:30 AM, the laboratory director failed to assure compliance with the applicable regulations and potentially may have harmed patients. The findings include: See D5779

D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy and procedure, personnel competency evaluation documents, and interview with the laboratory testing personnel 04/22/2024 at 11:30 AM, the laboratory director failed to ensure that the laboratory established policies and procedures for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. The findings include: The laboratory did not have a written policy and procedure to assess employee, see D5209.