Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0553321	05/17/2021
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 review of the laboratory's API (American Proficiency Institute) proficiency testing result reports in 2019, 2020 and the Q1 2021 PT records, and interview with the laboratory testing personnel (TP), it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in the CBC (complete blood cell count) testing was unsatisfactory analyte performance for the testing event. The findings included: a. The laboratory used Horiba Petra 60+C (Horiba) hematology instrument to perform CBC and report the following parameters: WBC, WBC with 5-part automated cell differential, RBC, Hemoglobin (Hgb), Hematocrit (Hct) and Platelet count (Plt). b. The laboratory enrolled its proficiency testing with API PT provider, to ensure the accuracy, reliability, and timely of the CBC testing, c. The laboratory attained scores of 0% for all the parameters identified in item (a) above in the 3rd 2019 the 3rd 2020 API PT events which were unsatisfactory analyte performance for the testing events. d. The laboratory performed in approximately 400 patient samples monthly. e. The laboratory TP affirmed (5/17 /21 @ 11:35 am) that the laboratory attained 0% for all the CBC parameters in both the 3rd 2019 and the 3rd 2020 API PT events which were unsatisfactory analyte performance for the testing events.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems

	activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the final patient test result reports from the End-user (destination point of the patient test result report), lack of instrument printouts, and interview with the laboratory testing personnel (TP), it was determined that the laboratory failed to retain patient test records for at least 2 years, including instrument printouts, transcribed data, and failed to ensure that the original and the transcribed/transmitted copy were retained or retrievable. The findings included: a. The laboratory used Horiba Pentra 60+C (Horiba) to perform complete blood cell count (CBC) testing and reported WBC, WBC with 5 parts automated cell differentials, RBC, Hemoglobin (Hgb), Hematocrit (Hct), and Platelet count (Plt). b. Beginning in January 2021, the laboratory used an interface computer system, CureMD, to transmit the patient test results directly from Horiba to the End-user, where the in-house providers can review and monitor the patient test results directly online. c. At the time of the survey (5/17 /21 @ 11:55 AM) the laboratory TP was not able to retrieve instrument printout of the patient test results performed previously. d. The TP affirmed that the instrument was not able to retrieve previous patient test results after the Horiba IT personnel completed the interface installation.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of lack of the records for laboratory's validation/verification of the newly installed computer interface system, CureMD, and interview with the laboratory testing personnel (TP), it was determined that the laboratory failed to perform and document the validation/verification of the new computer interface system to demonstrate that it can obtain performance specifications as the manufacturer claimed, and document all the activities to ensure the accuracy, reliability, and timely of the testing process from the point of data entry (whether interfaced or entered manually) to the final report destination/End-user. The findings included: a. The laboratory used Horiba Petra 60+C (Horiba) to perform CBC (complete blood cell count). b. The laboratory failed to show the documents that the newly installed interface computer system could demonstrate that it can obtain performance specifications as the manufacturer claimed, and failed to document all the activities to ensure the accuracy, reliability, and timely of the testing process from the point of data entry (whether interfaced or entered manually) to the final report destination/End-user.
D5801	TEST REPORT CFR(s): 493.1291(a)

	The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of the laboratory's patient test result reports, the report format, and interview with the laboratory testing personnel (TP), it was determined that the laboratory failed to have an adequate procedure or electronic system(s) in place to ensure test results and other patient-specific data were accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner or correcting the laboratory director's name. The findings included: a. The laboratory use Horiba Petra 60+C(Horiba) hematology analyzer to perform CBC (complete blood cell count). b. At the time of survey (5/17 /21 @ 12:15 PM), the laboratory pulled 6 patient's testing result reports between March and April 2021. c. The survey requested the laboratory to provide the instrument printouts to verify the accuracy of the patient test results. d. The laboratory failed to provide the patient's instrument printout (see D-5421) e. The patient test result reports showed incorrect laboratory director's name f. The laboratory TP acknowledged that the instrument could not print out the previous copies after the newly interface computer system been implemented in January 2021.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the laboratory's API (American Proficiency Institute) proficiency testing result reports in 2019, 2020 and the Q1 2021 PT records, and interview with the laboratory testing personnel (TP), it was determined that the laboratory director failed to ensure that the proficiency testing samples were tested as required. The findings included: a. The laboratory director failed to ensure the proficiency testing samples were tested as required. b. The laboratory used Horiba Petra 60+C hematology instrument to perform CBC and report the following parameters: WBC, WBC with 5-part automated cell differential, RBC, Hemoglobin (Hgb), Hematocrit (Hct) and Platelet count (Plt). c. The laboratory enrolled its proficiency testing with API PT provider to ensure the accuracy, reliability, and timely of the CBC testing, d. The laboratory failed to attain a score of 80% for any of the parameters identified in item (a) above in both of the 3rd 2019 the 3rd 2020 API PT events which were unsatisfactory analyte performance for the testing events, see D-2121.

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 review of lack of the records of instrument print-out patient test result reports, lack of the documents of validation/evaluation activities of the Horiba Petra 60+C (Horiba) hematology analyzer with an interface computer system, CureMD, and review of the laboratory's API (American Proficiency Institute) proficiency testing result reports in 2019, 2020 and the Q1 2021 PT records, and interview with the laboratory testing personnel (TP), it was determined that the laboratory director failed to assure the establishment and maintenance of acceptable levels of analytical performance for each test system the laboratory performed, and to assure good quality laboratory operation, and to ensure the accuracy, reliability, and timely of the patient test result reports from the point of data entry (whether interface or enter manually) to final report destination. The findings included: a. The laboratory director failed to maintain the acceptable levels of analytical performance for each test system the laboratory performed and failed to assure the good quality laboratory operation. b. The laboratory used Horiba to perform CBC and report the following parameters: WBC, WBC with 5-part automated cell differential, RBC, Hemoglobin (Hgb), Hematocrit (Hct) and Platelet count (Plt). c. Horiba IT engineer installed an interface computer system, CureMD, with Horiba analyzer, and implemented in January 2021, so that the End-user be able to review and monitor the patient's test results, see D-5421 and D-5801. d. The laboratory failed to retain the patient test result's instrument printouts for at least two years, see D-3031