Department of Health & Human Services
Centers for Medicare & Medicaid Services

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Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0553321	(X3) Date Survey Completed 01/09/2019
Name of Provider or Supplier Los Alamitos Hematology/Oncology	**Street Address, City, State** 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
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the severity of the deficiencies cited herein, the Condition for General Laboratory Systems was not met. The laboratory failed to follow the written laboratory policy and procedure to assess employee competency (See D6030, D6054); failed to at least twice annually (D6053). The laboratory failed to 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 (See D5291).
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 review of (10) random patient sampling from 01/25/2017 to 06/07/2018,

	review quality control documents, absence of laboratory policies and procedures and an interview with the laboratory personnel, it was determined that the laboratory failed to 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. a. On 01/09/2019 (survey date) no documentation could be retrieve to show that the laboratory had a written policy for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified. This correction process involves identification and resolution of the problem, and development of policies that will prevent recurrence. Policies for preventing problems that have been identified must be written as well as communicated to the laboratory personnel and other staff, clients, etc., as appropriate (D6030). b. The testing person confirmed on 01 /09/2019 12:00 that the laboratory did in have a written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems. C. The annual testing declaration 01/09 /2019 estimated 40,000 hematology tests resulted and reported.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the severity of the deficiencies cited herein, the Condition: Laboratories Performing Moderate Complexity Testing: Laboratory director was not met. The laboratory director of moderate complexity testing failed to ensure quality testing was monitored and evaluated for the overall quality of the analytical systems and to correctly identify problems for testing performed. (See D5791, D5891)
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the ABX pentra 60 ct hematology analyzer quality control (QC) record review, ten (10) random patient sampling from 01/25/2017 to 06/07/2018 and a testing personnel interview, the laboratory failed to have written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. The findings included: a. On 01/09/2018 (survey date), it was found that the laboratory had no written quality control (QC) policies and procedures. From 01/03 /2017 through 02/16/2018 the laboratory performed three (3) levels of hematology controls daily (in-use) and when quality controls failed they were repeated numerous

	times with no corrective action(s) documented. During this period the quality controls for all parameters of the complete blood count with automated differential (CDBD) periodically had exceeded the reference ranges; continuously repeated (numerous shifts and trends of controls) and yet no corrective actions were noted on the QC data reports. No corrective actions were documented for quality control failures which appeared as manual entry errors (control and patient samples run under wrong controls), when the quality controls did not meet the acceptable reference range criteria they were deleted from the levy-Jennings graph, yet no corrective actions responses were documented. b. On 01/09/2019 the testing person confirmed that no documentation was recorded for ongoing quality control mechanism to monitor, assess, and correct problems when identified. c. The laboratory testing declaration (01 /09/2019) estimated an annual hematology patient testing volume of 40,000.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, random review of ten (10) patients test reports from 01/25/2017 to 06/07/2018, and an interview with the testing person, it was determined that the laboratory failed to have a written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the post analytic quality assessment systems for 2017 and 2018 to the date of the survey. The Findings include: a. The surveyor requested on 01/09/2019 (survey date) documentation of ongoing quality assessment (QA) for the post analytic system includes assessing practices/issues related to test report monitoring and evaluating the accuracy and completeness of the laboratory's test reports and the laboratory's turn-around times and procedures for notification of test results. b. The testing person confirmed 01/09/2019 12:00 that the laboratory did not have a written policy and procedure to assess monitor and correct problem in the post analytical systems. c. No documentation could be retrieved at the time of the survey to indicate that the post analytic review was conducted by a designated person for an ongoing mechanism to monitor, assess and, when indicted, correct problems when identified.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the severity of the deficiencies cited herein, the Condition: Laboratories Performing Moderate Complexity Testing: Laboratory director was not met. The laboratory director, moderate complexity testing, failed to ensure that required under Subpart H of this part. See D6030.
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 the lack of laboratory personnel competency evaluation, the lack of laboratory written policies and procedures for assessing individual performances and interview with the testing person, the Laboratory Director failed to 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. (See D6053, D6054).
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 the lack of quality control(QC) records, a random sampling of (10) patient reports from 01/25/2017 to 06/07/2018, performance specification records, and interview with the testing person, it was determined that the laboratory director /technical superior for the period of 2017 and 2018 failed to establish a quality control program appropriate for testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that those levels were maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. (See D5791)
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 and the lack of documentation for competency assessments, and interview with the testing person, it was determined that the laboratory technical consultant (laboratory director) failed to perform and document the performance of individuals responsible for moderate complexity testing at least semiannually during the first year and yearly thereafter the individual tests patient specimens. The evaluations must include but are not limited to the following: a. No documentation could be retrieved to show that the testing personnel from 2017 and 2018 were evaluated during the first six months and annually thereafter for their responsibilities as testing personnel. The evaluation must include following: Direct observations of the testing performed (including sample handling, processing and testing) Monitoring the recording and reporting of results Direct observation of instrument maintenance Review of intermediate worksheets, quality control records. Assessment of testing previously analyzed specimens (external QC and proficiently testing) Assessment of problem solving skills b. The laboratory staff confirmed 01/09/2019 (survey date) that no competency assessments were performed and documented by the laboratory director/technical consultant. c. Based on the laboratory's annual testing declaration submitted 01/09/2019, the laboratory analyzed and reported 40,000 hematology (automated complete blood cell count) testing.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on review and lack of documentation of annual personnel competency records and interview with the technical consultant, it was determined that the technical consultant failed to evaluate and document competencies for one testing personnel responsible for moderate complexity testing. The findings included: a. No evidence could be retrieved for annual competencies for the testing personnel of moderate complexity testing in the year 2017 and 2018 performing moderate complexity testing for automated Complete blood counts with differential (CBCD) on the Horiba 60 analyzer. b. The laboratory technical confirmed 01/09/2019 12:00 (survey date) that testing personnel competency records could not be retrieved for the annual performance of the testing personnel for the year 2017 and 2018. c. The laboratory testing declaration form, signed by the laboratory Director on 01/09/2019 that the laboratory performs approximately 40,000 automated CBCD tests annually.