Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0930143	09/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Biological Laboratory, Inc	620 W Covina Blvd, San Dimas, 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 proficiency testing (PT) 2017 thru 2019 test result reports, and interview with the laboratory technical consultant (TC) and the laboratory manager (LM), it was determined that the laboratory failed to attain a score of at least 80 percents of acceptable responses for Partial Thromboplastin Time (PTT) in the first 2019 PT event excluding a PT desk review by this office on January 9, 2019 and closed the case on January 14, 2019. The findings included: a. The laboratory used Sysmex CA1500 to perform coagulation testing including PTT. b. In order to be in compliance for the accuracy of the PTT testing system annually, the laboratory enrolled its PT with American Association of Bioanalysts (AAB) PT provider. c. The laboratory attained score of 60 % for PTT in the first (Q1) PT 2019 event, which was unsatisfactory performance for the event. d. The laboratory performed PTT in approximately 240 patient specimens per month. e. The TC and LM affirmed (9/12 /2019 @ 2:10 PM) that the laboratory attained score of 60 % for PTT in the first (Q1) 2019 PT, which was unsatisfactory performance for the PT event.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

	This STANDARD is not met as evidenced by: Based on observation of the laboratory's digital thermometer (DT) displays, a Fisher Brand, review of the temperature records, and interview with the laboratory technical consultant (TC), the laboratory manager (LM) and the laboratory personnel (TP), it was determined that the laboratory failed to follow the manufacturer's instructions and to familiarize the digital thermometers features and functions, and in a manner that provides temperature recording within the laboratory's stated performance specifications for daily temperature monitoring and recordings. The findings included: a. The laboratory selected a DT to monitor its temperatures condition of the refrigerator and freezer storages. b. The DT is equipped with features, namely to indicate the following information: 1) current temperature; 2) "Min", the lowest temperature in the past (not know exact time in the past), 3) "Max", the highest temperature in the past (not know exact time), or 4) "Lo" and 5) Hi" a mode to set the acceptable temperature ranges for the storage conditions, and 6) reset. c. The laboratory has established an acceptable temperature range for the refrigerator storage condition between 2 to 8 Celsius (oC). d. At the time of survey (9/12/2019 @10:35 AM), observed a DT for the refrigerator #3, a "Min" temperature record indicated a 1.4 oC in the past, which was out of the acceptable temperature for refrigerator storage condition. e. Further observation of a DT for the freezer #2, a "Max" temperature was recorded at 4.9 oC which was outside of the laboratory's acceptable temperature range between -10 to -30 oC. f. Furthermore, the laboratory failed to indicate that the temperature conditions were monitored for all the Sundays, when the laboratory closed. g. The TC, LM and TP affirmed (9/12/2019 @ 11 AM) that the laboratory failed to properly train, monitor, and record the temperatures to maintain the storage temperature in acceptable conditions.
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 review of the laboratory's Liquid Chromatography-Mass Spectrophotometry (LC/MS) and Labgen Comtrom, a laboratory information system's (LIS) quality control (QC) records, and interview with the technical supervisor (TS), it was determined that the laboratory failed to follow its written QC policies and procedures (P&P) and previously validated performance specificities for its LC/MS testing systems and failed to monitor the accuracy and precision of the complete analytic process. The findings included: a. The laboratory used Shimazu model 8030 LC/MS and Labgen Comtrom, a LIS, to perform urine drug screen and confirmation and provided the concentrations of the confirmed analyte and finally generated a report for a total of 57 drugs and its metabolites. b. The laboratory performed three levels of

	quality control, namely Low, Mid, and High QCs. c. The laboratory used Westgard QC rules to monitor, assess and accept the daily QC run. d. Review of a Levey Jennings Chart for Test 1032: 6-MAM with a period of 9/5/2019 to- 09/09/2019 for three levels. e. The charts provided graphic as well as summaries as follows: * W =Westgard (Fixed) D** = Displayed Data Level W* mean SD D** Mean SD 1 125.0 37.5 142.2 16.9 2 725.0 87.5 684.9 65.5 3 2000 500.0 1355.6 133.6 f. Cumulative points from previously data before 09/05/2019 clumped together showed solid bars for each level QC on LJ chart, the TS was unable to explain the data at the time of survey (9/12/2019 @ 2 PM). h. The laboratory must familiarize the results and data reprented on the LJ charts to evalue and assess the laboratory performances.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation of the laboratory digital thermometer (DT) displays, a Fisher Brand, review of the temperature records, and interview with the laboratory technical consultant (TC), the laboratory manager (LM) and the laboratory personnel (TP), it was determined that the laboratory failed to document all corrective actions taken when test systems did not meet the laboratory's established performance specifications, mainly, monitoring digital thermometer, or methodologies that performed outside of established operating parameters or performance specifications. The findings included: a. The laboratory failed to document all corrective actions taken when the laboratory storage temperatures did not meet the laboratory established acceptable temperature ranges for refrigerators or freezers storage conditions, see D-5411
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation of the laboratory operations , review of the laboratory's records, and interview with the laboratory technical consultant (TC), the laboratory manager (LM) and the laboratory personnel (TP), it was determined that the laboratory failed to assure and review analytic systems quality assessment including the effectiveness of

	corrective actions taken to resolve problems, revision of policies and procedures and discussion of analytic systems quality assessment reviews with appropriate staff. The findings included: a. The laboratory failed the PT scores for PTT began in th 2018 PTs (PT desk review) and continued till the 1st 2019 PT, see D-2121 b. The laboratory failed to assure the training of the laboratory personnel to understand the features of a digital temperature implemented in the laboratory operation, see D-5411 and D-5781. c. The laboratory failed to notice the LIS system's data and the calibration performance between Westgard (Fixed) settings and Displayed Data means, see D-5441.
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 proficiency testing (PT) from 2017 thru 2019 test result reports, and interview with the laboratory technical consultant (TC) and the laboratory manager (LM), it was determined that the laboratory director failed to be responsible for assuring compliance with the applicable CLIA regulations pertaining to successful performance of PT samples tested as required for Partial Thromboplastin Time (PTT) in 2018 and 2019. The findings included: a. The laboratory attained score of 60 % for PTT in the first (Q1) 2019 PT event and a PT desk review on January 4, 2019, which were unsatisfactory performance for these events, see D-2121.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: D-6094 Based on observation of the laboratory operations, review of the laboratory's records, and interview with the laboratory technical consultant (TC), the laboratory manager (LM) and the laboratory personnel (TP), it was determined that the laboratory director failed to assure quality assessment programs were maintained to meet good quality of analytical performance for high complexity test system and to assure the quality of laboratory services provided. The findings included: a. The laboratory provides wide spectra of the clinical laboratory services including LC/MS, a high complexity testing. The laboratory failed to assure and maintain good quality of the laboratory operations, see D-6016 and D-5793.