Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0666419	04/26/2022
Name of Provider or Supplier	**Street Address, City, State**	
American Bio-Clinical Laboratories	2730 N Main St, 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
D5309	TEST REQUEST CFR(s): 493.1241(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's test requisitions, client complaint log, and interview with the laboratory technical supervisor on April 26, 2022, at 12:30 pm, the laboratory failed to accurately enter the test requisition information into the laboratory's information system (LIS) for 5 patients out of 15 patients, reviewed. The findings include: 1. The laboratory used a 3rd party foreign data entry service to enter the test requisition information into the laboratory's information system which inaccurately entered the data affecting patient care adversely. a) The laboratory did not enter RPR test into its LIS for the patient # 3202145. b) The laboratory did not enter HIV test into its LIS for the patient # 3103565. c) The laboratory did not enter HIV, T cell CD3/4/8 test into its LIS for the patient # 3083740. d) The laboratory did not enter UA test into its LIS for the patient # 3138866. e) The laboratory did not enter CMP test into its LIS for the patient # 3353767. 2. The laboratory technical supervisor on April 26, 2022, at 12:30 pm, confirmed that the laboratory missed data entry from the test requisition into the LIS. 3. The laboratory's testing declaration form, signed by the laboratory director on 4/25/2022, stated that the laboratory performed 6,049,813 tests, annually.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3)

	Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's test records, problem log, and interview with the laboratory technical supervisor on April 26, 2022, at 1:30 pm, the laboratory staff failed to follow procedure to accurately label and handle patient specimens for 3 patients out of 10 patients, reviewed. The findings include: 1. The laboratory collected patient sample at its patient service center (PSC). The staff at the PSC mislabeled the sample tube # 2720139 and 3301876 and did not draw lavender top tube for sample # 2925314. This caused sample rejection and adversely affected patient care. 2. The laboratory technical supervisor on April 26, 2022, at 1:30 pm, affirmed that the staff made mistake in labeling and handling the specimens. 3. The laboratory's testing declaration form, signed by the laboratory director on 4/25/2022, stated that the laboratory performed 6,049,813 tests, annually.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's quality assessment policy and procedure, and interview with the laboratory technical supervisor on April 26, 2022, at 1:40 pm, the laboratory failed to assess preanalytic systems quality. The findings include: 1. The laboratory received multiple complaints from the providers regarding inaccurate test order entry and it had problems in sample labeling and handling. However, the laboratory's quality assessment program was unable to monitor and improve the system. Some examples of quality assessment include monitoring the frequency of specimen handling problems, perform periodic or spot checks for accurate transfer of information into the LIS. The preanalytic systems 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. 2. The laboratory technical supervisor on April 26, 2022, at 1:40 pm, affirmed that the laboratory's quality assessment system needs to be improved in order to quality of the service provided and prevent adverse effect on the patient care. 3. The laboratory's testing declaration form, signed by the laboratory director on 4/25/2022, stated that the laboratory performed 6,049,813 tests, annually.
D5815	TEST REPORT CFR(s): 493.1291(h) When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing.

	This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's patients test records, test pending list, and interview with the laboratory technical supervisor on April 26, 2022, at 11:10 am, the laboratory failed to notify the ordering physicians regarding the delayed testing of 4 patients out of 10 patients, reviewed. The findings include: 1. The laboratory's test pending list showed that the tests were delayed, and the turnaround time was exceeded beyond the laboratory's average time, however, the laboratory did not determine the need to notify the ordering physician which might had affected patient care adversely. a) The laboratory received sample # 3652881 on April 20 but A1C test was still pending as of April 26 and exceeded the laboratory's average turnaround time, 3 days. b) The laboratory received sample # 3655492 on April 6 but urine Mg test was still pending as of April 26 and exceeded the laboratory's average turnaround time, 3 days. c) The laboratory received sample # 3645958 on April 14 but thyroglobulin test was still pending as of April 26 and exceeded the laboratory's average turnaround time, 3 days. d) The laboratory received sample # 3650701 on April 19 but thyroglobulin test was still pending as of April 26 and exceeded the laboratory's average turnaround time, 5 days. 2. The laboratory technical supervisor on April 26, 2022, at 11:10 am, affirmed that the tests were delayed, and the laboratory did not determine the criteria of notifying the ordering physician. 3. The laboratory's testing declaration form, signed by the laboratory director on 4/25/2022, stated that the laboratory performed 6,049,813 tests, annually.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, patient test records, and interview with the laboratory technical supervisor on April 26, 2022, at 2:40 pm, the laboratory director failed to ensure compliance with the applicable regulations. The findings include: See D5309, D5311and D5815.
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: Based on Surveyor review of laboratory's quality assessment policy and procedure,

	patients' test records and interview with the laboratory technical supervisor on April 26, 2022, at 1:40 pm, the laboratory director failed to ensure the quality of the laboratory service provided through effective quality assessment. The findings include: See D5391.