Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0999149	07/10/2023
Name of Provider or Supplier	**Street Address, City, State**	
Alpha Clinical Laboratory, Inc	3021 N San Fernando Blvd Ste C, Burbank, 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
D2105	ENDOCRINOLOGY CFR(s): 493.843(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 laboratory's proficiency testing records from AAB, and interview with the laboratory technical consultant on July 10, 2023, at 11:30 am, the laboratory failed to take remedial action after receiving an unacceptable analyte score for the TT4 test at the Q3 event in 2021. The findings include: 1. The laboratory participated in the AAB proficiency testing program for the year 2021 and 2022. It received an unacceptable 80% score for the TT4 test at the Q3 event in 2021. The laboratory's TT4 test results for one of the sample, #13, out of 5 samples provided by AAB, was unacceptable. The laboratory's reported result was 1.4 microgram/dL which was out of the acceptable 3 -5 microgram/dL range. However, the laboratory did not take any remedial action for the failure. Therefore, the accuracy of the patient test results reported by the laboratory during the proficiency testing event cannot be assured and might have harmed patients. 2. The laboratory technical consultant on July 10, 2023, at 11:30 am, affirmed that the laboratory did not take any remedial or corrective action for the analyte failure at the Q3 event in 2021. 3. The laboratory's testing declaration form, signed by the laboratory director on 6/26/2023 stated that the laboratory performs approximately 600 TT4 tests, 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 assessment policies and procedure, and interview with the laboratory technical consultant/supervisor on July 10, 2023, at 11:15 am, the laboratory failed to establish and follow policies and procedures to assess technical consultant/supervisor competency. The findings include: 1. The laboratory had 1 technical consultant/supervisor; however, it did not assess competency of the technical consultant/supervisor. Competency assessment applies to all persons that perform patient testing and/or report patient test results, including but not limited to, technical and clinical consultants, technical supervisors, general supervisors and other laboratory staff. Documented competency assessment is required for the following named positions on the Form 209: technical consultant, clinical consultant, technical supervisor, general supervisor. The laboratory must have policies and procedures to assess competency based on the position responsibilities listed in Subpart M and these assessments must be performed at a frequency determined by the laboratory. Therefore, the quality of the laboratory's work cannot be assured and might have harmed patients. 2. The laboratory technical consultant /supervisor on July 10, 2023, at 11:15 am, affirmed that the laboratory did not assess technical consultant/supervisor competency. 3. The laboratory's testing declaration form, signed by the laboratory director on 6/26/2023 stated that the laboratory performs approximately 56,060 tests, annually.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy and procedure, patient test results and interview with the laboratory technical consultant on July 10, 2023, at 12:20 pm, the laboratory personnel failed to follow the laboratory's policy & procedure when the automated chemistry analyzer produced AST test results with the abnl assay error message. The findings include: 1. The laboratory used Dimensiomn EXL 200 automated chemistry instrument to perform AST (SGOT) test. The instrument gave abnl (abnormal) assay error message for one patient (# 1061113) out of 15 samples reviewed. The laboratory must rerun the sample with the error message and troubleshoot before accepting the result, according to the policy & procedure. However, the laboratory did not rerun and reported the patient's result without any further analysis. The results showed a high value, 123 U/L which was out of the reference range. Therefore, the validity of the patients' test results rendered by the laboratory cannot be assured and might have harmed patient. 2. The laboratory technical consultant on July 10, 2023, at 12:20 pm, affirmed that the laboratory personnel did not follow the policy & procedure to resolve the error message problem.

	3. The laboratory's testing declaration form, signed by the laboratory director on 6/26 /2023, stated that the laboratory performs approximately 2,500 AST tests, annually.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's instrument function check and calibration, and interview with the laboratory technical supervisor on July 10, 2023, at 12:45 pm, the laboratory failed to do the instrument function check/calibration for 2 PCR instruments out of 2, reviewed. The findings include: 1. The laboratory used 7500 ABI PCR instruments to perform COVID-19 PCR test. The laboratory had 2 instruments; both instruments showed expired optical calibration. Since the instruments' optical calibration expired, it can not be assured that the instruments were functioning properly. Therefore, the quality of the test cannot be assured and might have harmed patients. 2. The laboratory technical supervisor on July 10, 2023, at 12: 45 pm, affirmed that the 7500 ABI PCR instruments' optical calibration expired, and the calibration is due. 3. The laboratory's testing declaration form, signed by the laboratory director on 6/26/2023 stated that the laboratory performs approximately 4,800 COVID-19 PCRT tests, annually.
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 Surveyor review of laboratory's quality assessment records, and interview with the laboratory technical consultant/supervisor on July 10, 2023, at 1:45 pm, the laboratory failed to establish 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 include: 1. The laboratory personnel failed to follow the laboratory's procedure to perform and troubleshoot the test error (see D5401) and the laboratory failed to perform the instrument performance check/calibration (see D5435) however, the laboratory did not establish the quality assessment policy and procedure to monitor, assess and correct problems in the analytic system. Hence, it did not find problems associated with the instrument function check and laboratory personnel not following the test procedure. Therefore, the quality and accuracy of the patients' test results rendered by the laboratory cannot be assured and might have

	harmed patients. 2. The laboratory technical consultant/supervisor on July 10, 2023, at 1:45 pm, affirmed that the laboratory did not establish an effective quality assessment policy and procedure to monitor and assess the problems found in the analytic systems. 3. The laboratory's testing declaration form, signed by the laboratory director on 6/26/2023 stated that the laboratory performs approximately 56,060 tests, annually.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy and procedure, patient test results and interview with the laboratory technical consultant on July 10, 2023, at 12:20 pm, the laboratory testing person #1 failed to follow the laboratory's policy & procedure when the automated chemistry analyzer produced AST test results with the abnl assay error message. The findings include: See D5401.
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, proficiency testing and patient test records, instrument function check and calibration, quality assessment records and interview with the laboratory technical consultant/supervisor on July 10, 2023, at 1:45 pm, the laboratory director failed to assure laboratory's compliance with the applicable regulations and thus had impaired the laboratory test quality and potentially harmed patients. The findings include: See D2105, D5209, D5401, D5435 and D5791.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. 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 consultant on July 10, 2023, at 12:20 pm, the laboratory director failed to assure that the laboratory personnel are performing the test methods as required for accurate and reliable results. The findings include: See D5401.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing records from AAB, and interview with the laboratory technical consultant on July 10, 2023, at 11:30 am, the laboratory director failed to assure that the laboratory followed an approved corrective action plan when any proficiency testing result is found to be unacceptable. The findings include: See D2105.
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 records, and interview with the laboratory technical consultant/supervisor on July 10, 2023, at 1:45 pm, the laboratory director failed to 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. The findings include: See D5791.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must 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 personnel competency assessment policies and procedure, and interview with the laboratory technical consultant/supervisor on July 10, 2023, at 11:15 am, the laboratory director failed to ensure that policies and procedures are established for monitoring technical consultant/supervisor competency to assure that they are competent. The findings include: See D5209.

D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's personnel records, and interview with the laboratory technical supervisor on July 10, 2023, at 10:40 am, the laboratory director failed to specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. The findings include: The laboratory reported 1 technical consultant/supervisor and 2 testing personnel on the form CMS-209 and 2 lab assistants on the form LAB 116. However, the lab director did not specify in writing the duties and responsibilities of each person.