Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0563772	07/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
Sun Clinical Laboratories	9349 Telstar Ave Ste A & B, El Monte, 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
D2047	PARASITOLOGY CFR(s): 493.829(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of the second quarter (Q2-2018) of the American Associations of Bioanalysts (AAB) proficiency testing records and interview with the Technical supervisors, it was determined; that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Parasitology (Identification, ID). The findings included: a. AAB reported an unsatisfactory score of 50% for Parasitlogy (ID). b. Based on the laboratory's annual testing declaration submitted for 2018-2019, the laboratory analyzed and reported 1,625 for Parasitlogy tests that results cannot be assured. c. The Technical supervisors confirmed (7/24/2019, 1600) that the laboratory received the above unsatisfactory proficiency testing score.
D2075	GENERAL IMMUNOLOGY CFR(s): 493.837(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 first quarter (Q1-2019) of the American Associations of Bioanalysts (AAB) proficiency testing records and interview with the Technical supervisors, it was determined; that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Rubella IgM analyte. The findings included: a. AAB reported an unsatisfactory score of 67% for Rubella IgM. b. Based on the

	laboratory's annual testing declaration submitted for 2018-2019, the laboratory analyzed and reported 7,334 for Rubella tests that results cannot be assured. c. The Technical supervisors confirmed (7/24/2019, 1600) that the laboratory received the above unsatisfactory proficiency testing score.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation and interview with the testing personnel and Technical supervisors, it was determined; that the laboratory lacks a flammable cabinet for storage chemicals and toxic reagents. The laboratory failed to observe Safety procedures to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. The findings included: a. The laboratory lacked storage of; Laboratory-grade flammable alcohols, Xylene, and staining reagents (Parasitology, Cytology, Hematology and Chemistry), including but not limited to hematoxylin and eosin. b. Patients pathology reports revealed that biopsy specimens were received in Formalin, a highly toxic liquid mixture of formaldehyde, methyl alcohol, and other soluble chemicals. c. Based on the laboratory's annual testing volume declaration submitted for 2018-2019, the laboratory analyzed and reported; Cytology and Histopathology 54,974, Parasitology 130, and Hematology 1,257,266 which uses flammable chemical s that are not stored properly. d. The technical supervisors confirmed (7/24/2019, 1600) that the laboratory did not have a flammable cabinet for chemical and biochemical storage.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of the American Association of Bioanalysts (AAB) proficiency testing records and interview with the Technical supervisors it was determined that; the laboratory failed to verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance. The findings included: a. Q1-2019, AAB reported an artificial 100% proficiency score for the following analytes. Homocysteine Spec.: Reported Grading Mean: Value: Range: 1# 3.9 4.2-9.2 6.68 Note: True score for Homocysteine should have been 50%. Protein, Total-Urine Chemistry Spec.: Reported Grading Mean Value: Range: 1? 8 8.1-13.5 10.79 Note: True score for Protein, Total-Urine Chemistry should have been 50%. Uric Acid-Urine Chemistry Spec.: Reported Grading Mean Value: Range: 1? 3.7 4.1-5.8 4.96 2? 5.2 5.3-7.5 6.42 Note: True score for Uric Acid- Urine Chemistry should have been 0%. Chloride-Urine Chemistry Spec.: Reported Grading Mean

	Value: Range: 1? 74 76-84 80.1 2* 160 163-180 171.5 Note: True score for Chloride-Urine Chemistry should have been 0%. Sodium-Urine Chemistry Spec.: Reported Grading Mean Value: Range: 1* 92 83-91 86.9 b. Q2-2019, AAB reported an artificial 100% proficiency score for the following analytes. Uric Acid-Urine Chemistry Spec.: Reported Grading Mean Value: Range: 2# 6.4 6.5-9.1 7.79 Note: True score for Uric Acid- Urine Chemistry should have been 50%. Bilirubin, Direct-Chemistry Spec.: Reported Grading Mean Value: Range: 3# 0.8 1.0-1.8 1.38 4# 0.8 1.0-1.8 1.41 Note: True score for Bilirubin, Direct Chemistry should have been 60%. c. Q3-2018, AAB reported an artificial 100% proficiency score for the following analytes: CMV- Virology Spec.: Reported Intended Value: Result: 3? Negative Positive Note: True score for CMV 70%. Abbreviation: Cytomegalovirus (CMV) d. The AAB has the following footnotes: ?= This score may not truly evaluate performance for these specimens which were not graded because of a lack of participants consensus. #= this method was not grade due to an insufficient number of peer respondents. No appropriate default grouping was available. The listed ranges should provide a reasonable guide to your performance, however exercise caution in evaluating your results. *= Out of grading range or incorrect respone. e. The testing personnel confirmed (7/24/2019, 1600) that the laboratory received the above artificial 100% scores and that the laboratory did not have a corrective action for the failures in the proficiency testing.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review and the lack of documentation to verify the accuracy of any test or procedure it performs that is not included in subpart I of this part and interview with the technical supervisors, it was determined; that the laboratory failed to at least twice annually verify the accuracy. The findings included: Hematology a. The laboratory has no documentation for the verification of accuracy for Sperm Motility and Morphology. b. Based on the laboratory's annual test volume submitted for 2018-2019, the laboratory analyzed and reported 274 Semen analyses which include Sperm Motility and Morphology which results cannot be assured. c. The technical supervisors confirmed (7/24/2019, 1600) that the laboratory has no documentation to verify the above tests. Immunohematology a. Q1-2018 AAB reported an unsatisfactory score of 50% for Direct Ant globulin Test (DAT). b. Based on the laboratory's annual test volume submitted for 2018-2019, the laboratory analyzed and reported 2,133 DAT tests that its results cannot be assured. c. The technical supervisors confirmed (7/24/2019, 1600) that the laboratory received an unsatisfactory proficiency test score. Chemistry a. AAB reported the following unsatisfactory proficiency testing score Analyte: Score: Event/Year: Folate 50% Q2-2017 b. Based on the laboratory's annual test volume submitted for 2018-2019, the laboratory analyzed and reported 5,877 Folate tests that its results cannot be assured. c. The technical supervisors confirmed (7/24/2019, 1600) that the laboratory received an unsatisfactory proficiency test score.
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 the review of patient reports, manufacturer's instructions (COBAS AmpliPrep) and interviews with technical supervisor, the laboratory failed to follow manufacturer's instructions for sample handling. The finding included: a. The laboratory uses: the COBAS AmpliPrep instrument for HBV and HCV analytes. b. The COBAS AmpliPrep Policy and Procedure stated: "Specimens and Controls should be handled as if infectious using safe laboratory procedure such as those outline in Biosafety in Microbiological and Biomedical Laboratories and the CLSI Document M29-A. Thoroughly clean and disinfect all work surfaces with a freshly prepared solution of 0.5% sodium hypochlorite in deionized or distilled water." c. The technical supervisor confirmed (7/24/2019, 1600), that the laboratory failed follow manufacturer's specimen handling protocol.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with the Technical supervisors and testing personnel (via phone conversation) it was determined that the laboratory had used reagent that had exceeded their expiration dates. The findings included. a. Based on observation on the day of the survey (7/24/2019), the McFarland standards (0.0, 0.5, 2.0, and 3.0) had an expiration date of 5/23/2019 for lot #A8113. b. Based on the laboratory's annual declaration submitted for 2018-2019, the laboratory analyzed and reported 8,054 susceptibility tests which results cannot be assured. d. The Technical supervisors and testing personnel (via phone conversation) confirmed (7/24/2019, 1600) that the laboratory failed to use non-expired reagents.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the lack of documentation of Sorval Cell Washer 2 maintenance records and interview with the laboratory Technical Supervisors, it was determined that; the laboratory failed to perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer for the laboratory Cell Washer 2. The findings included. a. The laboratory uses Sorval Cell Washer 2 used in Blood Bank. The manufacturer stated: "To ensure proper fill, press

	CHECK after beginning the first run. At the end of the fill step, the Cellwasher 2 will stop. Examine the level of saline in each tube. Fill is consider acceptable if; . the level of saline in all tubes is visible above the metal bands holding the tube, . the difference between the maximum fill and minimum fill is less than 0.7 mL or 3/8 inch for 12 mm tubes and 7/16 inch for 10 mm tubes." b. Based on the laboratory's testing declaration submitted for 2018-2019, the laboratory analyzed and reported 12,255 Blood Bank ABO, Rh group, and Antibody Detection (nontransfusion) tests for which the results cannot be assured. c. The Technical supervisors confirmed (7/24/2019, 1600) that the laboratory failed to follow manufacturer's instruction for the manufacturer and with at least the frequency specified by the manufacturer for the laboratory Cell Washer 2.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) 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 establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on the lack of calibration documentation, review of the laboratory's Digital Thermometer for BD Viper (for CT/GC) procedures, and interview with testing personnel, it was determined; that the laboratory failed to perform calibration for the Digital thermometer. The findings included: a. Examination of the laboratory's Digital Thermometer used for the specimen heating plate for BD Viper (for CT/GC) procedures, the laboratory failed to document the calibration procedure. b. Based on the laboratory's annual testing declaration submitted for 2018-2019, the laboratory analyzed and reported 61,935 CT/GC analytes that results cannot be assured. c. The testing personnel confirmed (7/24/2019, 1600) that the laboratory failed to calibrate the Digital Thermometer used in the BD Viper for CT/GC molecular analysis.
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 Individualized Quality Control Plan (IQCP), quality control (QC) logs, and interview with the laboratory's Technical supervisors it was

	determined that the laboratory failed to update the number, type, and frequency of testing control materials for the current media and reagents used in Bacteriology. The findings included: a. On the day of the survey (7/24/2019), the laboratory had no documentation presented to the surveyor for the current media and reagents (Remel) currently being used in Bacteriology. b. The laboratory's IQCP did not reflect the changes in media used from BD and Hardy to Remel. c. Based on the laboratory's annual declaration submitted for 2018-2019, the laboratory analyzed and reported 40,518 cultures which results cannot be assured. d. The Technical supervisors and testing personnel (via phone conversation) confirmed (7/24/2019, 1600) that the laboratory failed to include an update of the IQCP for the current culture media and reagents used.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of quality control documentation, observation of all culture media (Remel) and interview with the Technical supervisors and testing personnel (via phone conversation) , it was determined; that the laboratory failed to perform quality control (QC) testing on all culture media. The findings included: a. The laboratory did not check of sterility, ability to support growth, physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer of all the media used for cultures. b. The laboratory must document all control procedures performed. c. Based on the laboratory's annual declaration submitted for 2018-2019, the laboratory analyzed and reported 40,518 cultures which results cannot be assured. d. The Technical supervisors and testing personnel (via phone conversation) confirmed (7/24/2019, 1600) that the laboratory failed to perform and document; check of sterility, ability to support growth, physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer of all the media used for cultures.
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 review and the lack documentations and interview with Technical supervisors, it was determined that the laboratory failed to document all analytic

	systems assessment activities. See D 5411, D 5417, D 5429, D 5433, D 5431, and D 5477.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on review of documents and interview with the Technical supervisors and testing personnel, it was determined that; the laboratory director failed to ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. See D2047, D2075, D3011, D5215, D5217, D5411, D5417, D5429, D5433, D5441, and D5477.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the American Association of Bioanalysts (AAB) proficiency testing records and interview with the Technical supervisors and testing personnel it was determined that; the laboratory director failed to ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. See D 2047, D2075, D5215, and D5217,