Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1025536	06/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Sunrise Clinical Laboratory Inc	21216 Olean Blvd Ste 3, Port Charlotte, FL	

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
D0000	At the time of the announced, on-site recertification survey, Sunrise Clinical Laboratory was found to not be in compliance with the CLIA laboratory requirements of 42 CFR 493.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory staff, the laboratory failed to maintain complete proficiency testing records for 8 of 15 API (American Proficiency Institute) testing events reviewed. The findings include: On June 22, 2021 the laboratory's proficiency testing records were reviewed. The laboratory is enrolled with the API proficiency testing program for hematology, chemistry, and immunology. During the review of the 2019 - 2021 proficiency testing records, the errors listed below were identified: API 2019 proficiency testing Testing Event #3 - Chemistry The laboratory did not retain a copy of the signed attestation sheet. API 2020 proficiency testing Testing Event #1, #2, and #3 - Hematology The laboratory did not retain a copy of the signed attestation sheet. Testing Event #3 - Immunology The laboratory did not retain a copy of the signed attestation sheet. Testing Event #1 and

	#2 - Chemistry Miscellaneous The laboratory did not retain a copy of the signed attestation sheet. API 2021 proficiency testing Testing Event #1 - Immunology The laboratory did not retain a copy of the signed attestation sheet. During an interview on 6/22/21 at 10:00 AM, the General Supervisor confirmed the proficiency testing records were incomplete.
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 record review and staff interview, the facility failed to ensure yearly maintenance was performed on the Sysmex CA-500 coagulation instrument for 2020. The findings include: The maintenance guide for the Sysmex CA-500 states "1. Replace Rinse Filter - Replace the Rinse Filter yearly." The record review of the "Sysmex CA-500 Maintenance Checklist" for January - December 2020 showed the required yearly maintenance was not marked on the form as being completed. The interview with the General Supervisor on 6/22/21 at 12:15 PM confirmed the maintenance had not been performed.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility failed to perform the calibration verification at least once every 6 months for the Coulter ACT 5 diff hematology analyzer. Findings include: The record review on 6/22/21 of the calibration documentation for the hematology analyzer showed calibration was

	performed on 8/1/19, 12/16/20, and 5/20/21. The interview with the General Supervisor at 11:30am confirmed calibration had not been performed every 6 months as manufacturer instructions require.
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 record review and staff interview, the facility's quality assessment procedure failed to detect omissions in yearly maintenance for the coagulation analyzer and failed to identify calibrations of the hematology analyzer were not performed. The findings include: The quality assessment policy reviewed on 6/22/21 referenced checklists for preanalytic, analytic, and postanalytic activities. There were no filled out checklists in the manual. During an interview with the General Supervisor at 12: 30 PM on 6/22/21, he said that they did not use the checklists any more.