Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1025536	04/09/2019
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
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 proficiency testing records and interview with laboratory personnel, the laboratory did not maintain all of the proficiency testing records and did not have the required signatures on all of the documentation. Findings include: The surveyor reviewed the American Proficiency Institute (API) records for the past two years at 9: 45 a.m. on 04/09/2019 and found that the attestation and the performance evaluation for the third hematology testing event of 2018 were not signed. The laboratory received an unacceptable score of 72% for white blood cell differential, but there was no corrective action listed on the performance evaluation. During an interview with the technical consultant at 10:00 a.m. on 04/09/2019, he confirmed that the forms had not been signed and that there was no documentation to inidicate that corrective action had been taken. For the second testing event of 2018, the laboratory received an unacceptable score of 0% for High Density Lipoprotein (HDL) Cholesterol. The laboratory could not find the signed attestation, performance evaluation form, or

	documentation of corrective action. During an interview with the technical consultant at 10:00 a.m. on 04/09/2019, he confirmed that they could not locate the documentation for that event.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(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 record review and interview with laboratory personnel, the labortory failed to get an 80% for High Densitiy Lipoprotein (HDL) Cholesterol for the the second testing event of 2018. Findings include: Review of American Proficiency Institute (API) test results on 04/09/2019 revealed that the laboratory received a 0% for HDL Cholesterol for the second testing event of 2018. During an interview with the technical consultant at 10:00 a.m. on 04/09/2019, he confirmed that they had received an unacceptable score on that proficiency test and could not locate the paperwork..
D2122	HEMATOLOGY CFR(s): 493.851(b) 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 record review and interview with laboratory personnel, the labortory failed to get an 80% for white blood cell differential for the third testing event of 2018. Findings include: Review of American Proficiency Institute (API) test results on 04/09 /2019 revealed that the laboratory received a 72% for white blood cell differential for the third teting event of 2018. Four of five results for lymphocytes and thiee of five results for neutrophils were unacceptable. During an interview with the technical consultant at 10:00 a.m. on 04/09/2019, he confirmed that they had received an unacceptable score on that proficiency test.
D5393	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c) 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, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of policies and procedures and interview with laboratory personnel, the laboratory did not document all preanalytic systems quality activities. Findings include: The surveyor reviewed of the quality assessment policy on 04/09/2019, and found that it referenced checklists for preanalytic, analytic, and postanalytic activities. There were no filled out checklists in the manual. During an interview with the

	technical consultant at 10:45 a.m. on 04/09/2019, he said that they did not use the checklists any more.
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 of policies and procedures and interview with laboratory personnel, the laboratory did not document all analytic systems quality activities. Findings include: The surveyor reviewed of the quality assessment policy on 04/09/2019, and found that it referenced checklists for preanalytic, analytic, and postanalytic activities. There were no filled out checklists in the manual. During an interview with the technical consultant at 10:45 a.m. on 04/09/2019, he said that they did not use the checklists any more.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic 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 postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of policies and procedures and interview with laboratory personnel, the laboratory did not document all postanalytic systems quality activities. Findings include: The surveyor reviewed of the quality assessment policy on 04/09/2019, and found that it referenced checklists for preanalytic, analytic, and postanalytic activities. There were no filled out checklists in the manual. During an interview with the technical consultant at 10:45 a.m. on 04/09/2019, he said that they did not use the checklists any more.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on interview with laboratory personnel and lack of documentation, the technical consultant did not document performance evaluations of three of three personnel who did moderate complexity testing. Findings include: During an

	interview with the technical consultant at 10:00 a.m. on 04/09/2019, he said that he had not documented annual competency evaluations of the testing personnel.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on proficiency testing records and interview with laboratory personnel, the laboratory director did not ensure that proficiency test results were reviewed or that corrective action was required. Findings include: The surveyor reviewed the American Proficiency Institute (API) records for the past two years at 9:45 a.m. on 04 /09/2019 and found that for the third hematology testing event of 2018, the laboratory received an unacceptable score of 72% for white blood cell differential. There was not signature on the performance evaluation form, and no corrective action was documented. For the second testing event of 2018, the laboratory received an unacceptable score of 0% on High Density Lipoprotein (HDL) Cholesterol. The laboratory could not locate the signed attestation, performance evaluation, or documentation of corrective action. During an interview with the technical consultant at 10:00 a.m. on 04/09/2019, he confirmed that there was no documentation to indicate that corrective action had been taken. For the second testing event of 2018, the laboratory received an unacceptable score of 0% for High Density Lipoprotein (HDL) Cholesterol. The laboratory could not find the signed attestation, performance evaluation form, or documentation or corrective action. During an interview with the technical consultant at 10:00 a.m. on 04/09/2019, he confirmed that they could not locate the documentation for that testing event.