Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D2199977	06/01/2026
Name of Provider or Supplier	**Street Address, City, State**	
Sunrise Medical Laboratories, Inc	279 Chase Ave, Waterbury, CT	

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
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 record review and staff interview, the laboratory failed to establish competency assessment policies and procedures to assess competency for the regulatory responsibilities for the clinical consultant (CC). Findings include: 1. Record review on 06/01/2026 of the staff training and competency files revealed lack of competency assessment policies and documented competency assessment records for the regulatory position of CC. 2. Staff interview on 06/01/2026 at 12:20 PM with the Laboratory Director confirmed the above finding.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation, record review and staff interview, the laboratory failed to follow their established policies and procedures and document the open date and expiration date of quality control (QC) material in the specialty of hematology.

	Findings include: 1. Surveyor observation on 06/01/2026 at 10:30 AM of the hematology laboratory refrigerator revealed the following liquid QC in use: a. 'EIGHTCHECK X-TRA-L: i. Lot number: 60760710 ii. Manufacturer expiration date: 2026-06-24 b. 'EIGHTCHECK X-TRA-N: i. Lot number: 60760711 ii. Manufacturer expiration date: 2026-06-24 c. 'EIGHTCHECK X-TRA-H: i. Lot number: 60760712 ii. Manufacturer expiration date: 2026-06-24 d. Lack of documentation of an open date and laboratory assigned expiration date from open date. 2. Record review on 06 /01/2026 of the laboratory's 'CBC/PLT with 3-Part Differential' standard operating procedure revealed the following: a. 'Unopened and properly stored, EIGHTCHECK X-TRA is table until the expiration date stated on the vial'. b. 'Open vial stability is 14 days when promptly refrigerated after each use'. c. 'Record the date on each vial upon opening'. 3. Staff interview on 06/01/2026 at 10:35 AM with the laboratory Testing Personnel #1 confirmed the above findings. 4. The laboratory performs 1500 tests annually in the specialty of hematology.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) (b)(1)(i) 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. (b)(1)(ii) 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 surveyor observation, record review and staff interview, the laboratory failed to perform and document annual room temperature thermometer function checks in the specialty of hematology. Findings include: 1. Surveyor observation on 06 /01/2026 at 9:45 AM of the hematology laboratory revealed a 'Traceable' brand thermometer on the wall with a serial number of 221156799 and an expiration date of 01/17/2024. 2. Record review on 06/01/2026 of the laboratory's 'Room Temperature Thermometer Calibration' log revealed lack of annual calibration documentation for the above room temperature thermometer listed in 1 above. 3. Revord review on 06/01 /2026 of the laboratory's 'Temperature Protocol' policies and procedures revealed 'All thermometers are certified annually by a NIST traceable thermometer'. 4. Staff interview on 06/01/2026 at 12:10 PM with the Laboratory Director confirmed the above findings. 5. The laboratory performs 1500 tests annually in the specialty of hematology.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b) (1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document corrective action when room temperature fell outside of the established acceptable range in the specialty of hematology. Findings Include: 1. Record review on 06/01 /2026 of the laboratory's 'Room Temp Chart' revealed the following: a. The acceptable temperature range is 15 to 25 degree Celsius. i. Lack of documentation of corrective action for the following days when the room temperature was outside of the acceptable range listed in 1(a) above: I. 59 of 177 working days in 2025. II. 12 of 76 working days in 2026. 2. Record review on 06/01/2026 of the phlebotomy 'Room Temp Chart' revealed the following: a. The acceptable temperature range is 15 to 25 degree Celsius. i. Lack of documentation of corrective action for the following days when the room temperature was outside of the acceptable range listed in 2(a) above: I. 49 of 190 working days in 2025. II. 12 of 75 working days in 2026. 3. Record review on 06/01/2026 of the laboratory's 'Temperature Protocol' policies and procedures revealed 'Anytime there is a discrepancy in temperature range or any malfunction of a thermometer this must be reported to the management team. The management team will investigate and determine if a replacement refrigerator/freezer is warranted or a thermometer needs replacing', 4. Staff interview on 06/01/2026 at 12:05 PM with the Laboratory Director confirmed the above findings. 5. The laboratory performs 1500 tests annually in the specialty of hematology.
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure the reference interval on the patient final test report is accurately identified in the specialty of hematology. Findings include: 1. Record review on 06/01/2026 of the laboratory's 'CBC/PLT with 3-Part Differential Appendix B' standard operating procedure (SOP) versus one of one patient final test report revealed the following reference interval discrepancies: a. Patient#1 final test report i. Red Blood Cell (RBC) I. Test report reference interval: 4.40 - 6.10 MILL/CMM II. SOP reference interval: 4.40 - 6.00 MILL/CMM ii. Mean Corpuscular Hemoglobin Concentration (MCHC) I. Test report reference interval: 31.0 - 36.0 g/dL II. SOP reference interval: 32.0 - 35.0 g /dL 2. Staff interview on 06/01/2026 at 12:25 PM with the Laboratory Director confirmed the above findings. 3. The laboratory performs 1500 tests annually in the specialty of hematology.