Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	02D1087950	11/20/2024
Name of Provider or Supplier	**Street Address, City, State**	
Midnight Sun Oncology Partners	2490 South Woodworth Lp, Suite 499, Palmer, AK	

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 a review of 2023 and 2024 proficiency testing (PT) records and an interview with the testing person, the laboratory failed to include five (5) of seven (7) PT attestation forms indicating the PT samples were tested in the same manner as patient samples. Findings include: 1. A request was made to review the PT attestations for Hematology PT for 2023 and 2024, and the attestations for the second and third events of 2023 and all three events for 2024 could not be provided. 2. The testing person confirmed these findings during an in-person interview on 11/20/2024 at 12:00 PM. 3. The laboratory reports performing approximately 3,900 complete blood counts (CBCs) 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 a procedure review, review of competency records, and an interview with the Testing Person (TP), the laboratory failed to establish and follow written policies and procedures to assess employee competency for one (1) of two (2) testing persons. Findings include: 1. The Laboratory General Policy states "Each laboratory testing personnel file will have documentation of training, experience and yearly competency review." The policy did not establish instructions for semiannual assessment during the first year of testing. 2. A request was made to review competency assessments for TP1, hired in April 2023, and semiannual and annual competency assessments could not be provided. 3. The testing person confirmed these findings during an in-person interview on 11/20/2024 at 12:00 PM. 4. The laboratory reports performing approximately 3,900 complete blood counts (CBCs) annually.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of patient charts and an interview with the testing person, the laboratory failed to document the date, time, test results, and person to whom the panic or alert were reported in three (3) of three (3) patients who had critical or panic values. Findings include: 1. A request was made to review documentation of results notification when critical or panic values were obtained for complete blood counts (CBC). a. Patient #s 7902, 9779, and 3380 had critical or panic values reported; no provider notification was documented. 2. The testing person confirmed these findings during an in-person interview on 11/20/2024 at 12:00 PM. 3. The laboratory reports performing approximately 3,900 complete blood counts (CBCs) annually.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper

	storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of temperature and humidity log sheets, manufacturer specifications, and an interview with the testing person, the laboratory failed to monitor the room temperature and humidity from January 2023 through November 20, 2024, in the room where the Beckman Coulter DxH 520 Hematology analyzer was used for patient testing. Findings include: 1. The daily temperature and humidity log sheets did not contain the actual temperature and humidity readings, but a minimum and maximum temperature of 63/83 degrees F and humidity of 21/66 % was recorded for every date of patient testing. 2. The specification sheet for the Beckman Coulter DxH 520 lists the operating temperature of 64.4-89.6 degrees F, and less than 80% relative humidity. 3. The testing person confirmed these findings during an in-person interview on 11/20/2024 at 12:00 PM. 4. The laboratory reports performing approximately 3,900 complete blood counts (CBCs) annually.
D5807	TEST REPORT CFR(s): 493.1291(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 a review of patient test reports and an interview with the testing personnel, the laboratory failed to have separate reference or normal ranges for hemoglobin and hematocrit for male and female patients. Findings: 1. A review of final test reports for male and female patients revealed the laboratory failed to have separate reference ranges for male and female patients for hemoglobin and hematocrit. 2. The testing person confirmed these findings during an in-person interview on 11/20/2024 at 12:00 PM. 3. The laboratory reports performing approximately 3,900 hemoglobin and hematocrit tests annually.