Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	02D1087950	06/12/2018
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
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 did not establish or have written policies and procedures to assess the Technical Consultant's competency. Findings: 1. The Technical Consultant was hired on 7/15/16. 2. A review of the laboratory personnel's training and competency records for 2016, 2017, and 2018 revealed there was no training or competency assessment for the Technical Consultant. 3. During an interview on 6/12/18 at 10:00 am, the laboratory testing person confirmed the above findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory did not verify the

	reportable range on the Beckman Coulter AcT Diff 2 Hematology Analyzer prior to testing patients. Findings: 1. A review of the verification documentation showed the Beckman Coulter AcT Diff 2 Hematology Analyzer was put into use for patient testing on 8/31/16. 2. The reportable ranges for White Blood Cell counts, Red Blood Cell counts, Hemoglobin, and Platelet counts were verified on 10/28/16 and reviewed by the Laboratory Director on 11/8/16. 3. The laboratory does approximately 285 Complete Blood Counts per month on the analyzer. 4. During an interview on 6/12/18 at 1:00 pm, the laboratory testing person confirmed the above findings.