Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	02D0869756	08/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Katmai Oncology Group	3851 Piper Street, Suite U340, Anchorage, 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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on policy review and staff interview, the laboratory did not follow the manufacturer's instructions for reporting Hematology automated differentials. Findings: 1. The laboratory is using a Sysmex XT-2000i for complete blood counts (CBC) including automated differentials. 2. The analyzer suppresess abnormal results that potentially affect the accuracy of the test parameter resulting in an 'error' in the auto differential results. These potentially inaccurate results can be found in the 'research' screen of the analyzer. 3. According the to the Sysmex XT-2000i Instructions for use, "Parameters for research are displayed on the Research Screen. The analysis result cannot be used as data for reporting." 4. The results from the research screen were used for patient results and reported when the analyzer showed error flags on the auto differential. 5. The laboratory does approximately 7,365 CBCs annually. 6. The laboratory director confirmed these findings on 8/15/19 at 12:00 pm.
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory

	director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on review of the CMS116 application, credentialing documents such as college diplomas, and staff interview, the laboratory was performing peripheral smear reviews, including the reporting of abnormal red blood cell morphology and immature white blood cells categorized by the Food and Drug Administration (FDA) as high complexity testing. The laboratory director did not qualify to be a director for high complexity testing. Findings: 1. The CMS116 application listed two physicians performing peripheral smear reviews using a microscope. 2. The smear findings were entered electronically in the patient chart notes. 3. The laboratory was unaware that smear reviews with abnormal findings are categorized by the FDA as high complexity. 4. The laboratory performs approximately 38 peripheral smear reviews annually. 5. The laboratory director has a Bachelor of Science, and does not meet the qualifications for high complexity testing. 7. The laboratory director confirmed these findings on 8/15/19 at 12:00 pm.