

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D2280002	(X3) Date Survey Completed 11/20/2024
Name of Provider or Supplier Katmai Oncology Group, Llc	Street Address, City, State 12001 Business Blvd Ste 3c, Eagle River, 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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on an off-site desk review of the laboratory's 2024 College of American Pathologists (CAP) proficiency testing (PT) records and an email with the laboratory director, it was determined the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for the analyte Cell Identification/WBC Differential in two (2) out of three (3) Hematology testing events resulting in unsuccessful PT performance. Refer to D2130</p>
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</p>

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on an off-site desk review of the laboratory's 2024 College of American Pathologists (CAP) proficiency testing (PT) records and an email with the laboratory director, it was determined the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for the analyte Cell Identification/WBC Differential in two (2) out of three (3) Hematology testing events resulting in unsuccessful PT performance. Findings include: 1. Desk review of the laboratory's 2024 CAP PT records revealed analyte scores of less than eighty percent for Hematology Cell Identification/WBC Differential . a. 2024 Event 2 = 60% b. 2024 Event 3 = 60% 2. In an email correspondence with the laboratory director on November 7, 2024, it was confirmed the laboratory was unsuccessful in the PT events listed above.