

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  02D2280002	<b>(X3) Date Survey Completed</b>  08/30/2023
<b>Name of Provider or Supplier</b>  Katmai Oncology Group, Llc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Individual Quality Control Plan (IQCP), Quality Control (QC) records, and an interview with the laboratory director, the laboratory did not follow their IQCP for the Abaxis Piccolo Chemistry analyzers when performing QC for the BMP+ cartridges for 3 of 3 months since patient testing began on 5/3/2023. Findings include: 1. The Quality Control Plan states two levels of external controls are to be performed every thirty days, and with each new lot or shipment of cartridges on each Piccolo analyzer. 2. A review of QC records showed the laboratory failed to follow it plan to perform two levels of external QC every thirty days, and with each new lot or shipment of cartridges on each Piccolo analyzer. a. New lot QC on 8/16/23 did not include two levels of external QC on each Piccolo. b. Quality control records showed no entries for June or July 2023. 3. The lab director confirmed these findings on 8/30/2023 at approximately 11:45 AM. 4. The laboratory estimates approximately forty chemistry tests annually.</p>