

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  02D0869756	<b>(X3) Date Survey Completed</b>  08/31/2023
<b>Name of Provider or Supplier</b>  Katmai Oncology Group	<b>Street Address, City, State</b>  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.		

<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 analyzer when performing QC for the BMP+ cartridges for three of three months of QC reviewed. 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 nine of nine QC records for June, July, and August of 2023 showed the laboratory failed to follow its plan to perform two levels of external QC on each Piccolo analyzer with each new lot or shipment of BMP+ cartridges. 3. The lab director confirmed these findings on 8/31/2023 at approximately 12:00 PM. 4. The laboratory estimates approximately 1060 chemistry tests annually.</p>