

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D0869756	(X3) Date Survey Completed 11/10/2025
Name of Provider or Supplier Katmai Oncology Group	Street Address, City, State 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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of policies and procedures, lack of documentation, and an interview with the laboratory director (LD), the laboratory failed to fully establish procedures and follow quality assessment activities described in the "Patient Results Review" procedure since August 2023. The findings include: 1. A review of the procedure "Patient Results Review" listed quality assessment activities to review calculations, linearity, clerical error, unusual results, critical values and provider notification, and performance of reflex testing. 2. A request for documentation of performing quality assessment activities was made but documentation was not available. 3. An on-site interview with the LD on 11/10/25 at 12:00 PM confirmed there was no documentation. 4. The laboratory reports performing 50650 tests annually.</p>
D5309	<p>TEST REQUEST CFR(s): 493.1241(e)</p> <p>(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.</p> <p>This STANDARD is not met as evidenced by: Based on review of policies and procedures, lack of documentation, and interviews</p>

with testing personnel one (1) and the laboratory director (LD), the laboratory failed to ensure patient orders entered from the electronic health record (EHR) into the laboratory information system (LIS) were transcribed accurately since August 2023. The findings include: 1. A review of the policies and procedures manual revealed a lack of documented process for transcribing orders from the EHR to the LIS. 2. A request for documentation of audits or activities that checked the accuracy of transcription was made but documentation was not available. 3. In an on-site interview with TP1 on 11/10/2025 at 11:30 AM confirmed no procedure was available and with LD on 11/10/2025 at 12:00 PM confirmed that no audits or activities were performed. 4. The laboratory reports performing 50650 tests annually.

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

This STANDARD is not met as evidenced by:
Based on lack of procedures and documentation, record review, and an interview with the laboratory director, the laboratory failed to perform a comparison of test results twice a year for magnesium and lactate dehydrogenase (LD) performed on two of two Piccolo Express analyzers since August 2023. The findings include: 1. A review of policies and procedures failed to include procedures for comparison of magnesium and LD results between analyzers. 2. A request was made for documentation of analyzer comparisons for magnesium and LD performed on the Piccolo Xpress analyzers P06393 and P06805 but was not available. 3. An on-site interview with the laboratory director confirmed comparison of Piccolo Express analyzers P06393 and P06805 performing magnesium and LD was not done. 4. The laboratory reports performing 1588 magnesium and LD tests annually.