

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0304240	(X3) Date Survey Completed 05/02/2023
Name of Provider or Supplier J Michael Karst Md Pa	Street Address, City, State 4485 Atlanta Highway, Montgomery, AL	
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
D5793	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c)</p> <p>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on reviews of Hematology Quality Control (QC) records, Quality Assurance (QA) records, and an interview with the Testing Personnel, the laboratory failed to implement and document additional corrective actions to ensure patient CBC's (Complete Blood Counts) were only performed on days when at least two levels of QC were within acceptable ranges. The surveyor noted 27 patient CBC's were performed and reported on six days when QC was unacceptable from September 2021 through February 2023. The findings include: 1. A review of Hematology QC and patient records revealed the following: A) 9/29/2021: Normal QC out and no High QC; 7 patient CBCs B) 9/30/2021: High QC out and no Low QC; 2 patient CBCs C) 10/1/2021: Low QC out and no High QC; 6 patient CBCs D) 10/18/2021: Normal and High QC out; 2 patient CBCs E) 8/1/2022: Low and High QC out; 3 patient CBCs F) 2/8/2023: Low, Normal and High QC out; 7 patient CBCs 2. A review of the patient CBC printouts revealed the Laboratory Director had signed the above results, however there was no indication of whether he had been aware of the unacceptable QC performance on the date of the patient testing. 3. A review of the QA records for September 2021, October 2021 and August 2022 revealed the same testing personnel (no longer employed at the laboratory) had performed the QC on the dates listed above (A through E). Corrective action documented was to reeducate the testing personnel on the importance of proper mixing, and ensuring QC was acceptable before performing patient testing. 4. A review of the February 2023 QA records</p>

revealed a different testing personnel had performed the QC on 2/8/2023. Corrective action documented was "TP [Testing Personnel] released from her position". 5. During an interview on 5/2/2023 at 1:15 PM, the surveyor reviewed the above concerns with the Testing Personnel, and confirmed the corrective actions implemented so far had not corrected the problem. The laboratory needed to implement addition mechanisms to ensure the less experienced testing personnel only ran patient CBC's when at least two levels of QC were within acceptable ranges.
SURVEYOR ID #32558 Licensure and Certification Surveyor