Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0304240	05/30/2025
Name of Provider or Supplier	**Street Address, City, State**	
J Michael Karst Md Pa	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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the Policy and Procedure (P&P) Manual and an interview with the Testing Personnel 1 (TP1), the Laboratory Director (LD) failed to document review and approval of the new Complete Blood Count (CBC) procedure performed on the Beckman Coulter (BC) DxH 500 analyzer. The surveyor noted the BC DxH 500 procedure was in the P&P manual but had no evidence of approval by the LD before patient testing began on 08-15-2023 through the date of the current survey on 05-30-2025. The findings include: 1. A review of the P&P Manual revealed the new CBC procedure for the BC DxH 500 Hematology analyzer had no documentation of the LD's review and approval (as indicated by his signature and date) before patient testing began on 08-15-2023. 2. During the exit conference on 05-30-2025 at 12:07 PM, TP1 confirmed the above findings.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on a review of the Beckman Coulter (BC) DxH 500 Hematology analyzer verification records and an interview with Testing Personnel 1 (TP1), the Laboratory Director (LD) failed to document review and approval of the installation procedures

	as verification of the manufacturer's performance specifications before patient testing began. The surveyor noted the missing documentation from the date of installation, 08-15-2023 to the date of the current survey, 05-30-2025. The findings include: 1. A review of the verification records for the BC DxH 500 Hematology analyzer revealed no documentation of the LD's review and approval (as indicated by signature and date) of installation procedures verifying the manufacturer's performance specifications. Patient Complete Blood Count (CBC) testing began 08-15-2023. 2. A further review of the Hematology Method Comparison cover page revealed the LD failed to sign and date the evaluation to indicate review and approval of the data. 3. During the exit conference on 05-30-2025 at 12:07 PM, TP 1 confirmed the above findings.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on a review of the personnel records and interviews with Testing Personnel 1 (TP1), the Technical Consultant (TC) failed to ensure competency assessments for Testing Personnel (TP) listed on the CMS-209 (Laboratory Personnel Report), performing moderate complexity tests included all six CLIA minimal regulatory requirements. The surveyor noted two of the six requirements were missing on the semi-annual and annual competencies. The findings include: 1. A review of the 2023-2025 personnel records revealed TP competency assessments for the Hematology specialty had no documentation for two of the six CLIA minimal regulatory requirements. The missing two requirements were as follows: (1) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. (2) Assessment of problem-solving skills. 2. The TP1 confirmed the above findings during the exit conference on 5-30-2025 at 12:07 PM.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of Personnel records and an interview the Testing Personnel 1 (TP1), the Technical Consultant (TC) failed to assess competency of Testing Personnel (TP) at least semi-annually during the first year of patient testing. This was noted for one of the two TP listed on the CMS 209 (Laboratory Personnel Report) from 2023-2025. The findings include: 1. A review of Personnel records revealed TP2 had no evidence of semi-annual competency assessment available for review during the survey. 2. The TP1 confirmed the above findings on 05-30-2025 at 12:07 PM during the exit conference.

D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually This STANDARD is not met as evidenced by: Based on a review of Personnel records and an interview the Testing Personnel 1 (TP1), the Technical Consultant (TC) failed to perform competency assessment of the Testing Personnel (TP) annually. This was noted for one of the two TP listed on the CMS 209 (Laboratory Personnel Report) from 2023-2025. The findings include: 1. A review of Personnel records revealed TP1 had no evidence of an annual competency assessment performed and completed for 2023. 2. The TP1 confirmed the above findings on 05-30-2025 at 12:07 PM during the exit conference.