Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0304240	08/19/2021
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
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of the calibration and calibration adjustment records for the Beckman Coulter AcT diff Hematology analyzer, reviews of the laboratory's Coulter AcT diff Procedure, and the calibration instructions in the Operator's Manual, a review of Quality Control (QC) records, and interviews with the Technical Consultant, the laboratory failed to: I) Perform a calibration every six months as per laboratory procedure; II) Perform a calibration when critical parts were replaced, as per laboratory procedure; III) Perform and document the Reproducibility and Carryover before calibrating the instrument, as per manufacturer's instructions; IV) Verify calibrations and calibration factor adjustments by running at least two levels of QC, as per manufacturer's instructions. This was noted on calibrations and calibration factor adjustments performed from January 2019 thru July 2021. The findings include: I) 1. A review of the laboratory's Coulter AcT diff Procedure (Page 4 of 13), under "Calibration" revealed, "...The laboratory must verify calibration every six months ...". 2. A review of calibrations and calibration factor adjustments records revealed the laboratory performed a calibration using the S-CAL calibrator on 1/10/2019, 2/6

	/2020, and 2/11/2021. There was no documentation of a calibration performed the second half of 2019 or 2020. 3. During the exit conference at 3:20 PM on 8/19/2019, the Technical Consultant stated the testing personnel were supposed to perform calibrations twice a year, however he did not know where the documentation might be. II) 1. A review of the laboratory's Coulter AcT diff Procedure (Page 4 of 13), under "Calibration" revealed, "...The laboratory must verify calibration every six months ... .Calibration verification is also required if one or more of the following occur: Critical parts are replaced ...". 2. A review of laboratory records revealed the WBC (White Blood Cell) Chamber was replaced on 4/29/2019; there was no documentation of a calibration. 3. A review of calibrations and calibration factor adjustments records revealed the Sample Aspiration Syringe was replaced on 4/30 /2020; there was no documentation of a calibration. 4. During a review of the records on 8/19/2021 at 2:00 PM, the Technical Consultant confirmed a calibration was not performed on 4/29/2019 or 4/30/2020, when critical parts were replaced. III) 1. A review of the Beckman Coulter AcT diff Operator's Manual under Calibration on page 5-2 revealed, "BEFORE CALIBRATING Before calibrating, you must first prepare the instrument: ...2. Do Reproducibility. 3. Do Carryover. ..." 2. A review of calibrations and calibration factor adjustments records revealed the following: A) Calibration performed 1/10/2019; there was no documentation of Carryover studies B) Calibration performed 2/11/2021; there was no documentation of Carryover studies 3. During a review of the records on 8/19/2021 at 2:00 PM, the Technical Consultant confirmed the above noted findings. IV) 1. A review of the Beckman Coulter AcT diff Operator's Manual under Calibration revealed, "...16. Verify calibration by running 4C PLUS cell control. ...". 2. A review of calibrations and calibration factor adjustments records revealed the following: A) Calibration factor adjustment on 3/21/2019 at 10: 16 AM; no QC was performed afterwards B) Calibration factor adjustment on 10/31 /2019 at 11:07 AM; all three levels of QC performed afterwards (11:11, 11:12 and 11: 14 AM) were outside of acceptable ranges C) Calibration factor adjustment on 11/11 /2019 at 4:03 PM; Low and Normal QC were performed the following morning, however the Low QC was outside acceptable ranges D) Calibration factor adjustment on 12/12/2019 at 11:55 AM; no QC was performed afterwards E) Calibration performed on 2/6/2020 at 12:48 PM; the Low and Normal QC performed afterwards were outside acceptable ranges F) Calibration factor adjustment on 8/27/2020 at 12:04 PM; no QC was performed afterwards G) Calibration factor adjustment on 9/24/2020 at 11:44 AM; all three level of QC performed afterwards were outside acceptable ranges H) Calibration factor adjustment on 10/15/2020 at 9:40 AM; only one level of QC was performed afterwards, with no documentation of a second level of QC run I) Calibration factor adjustment on 11/19/2020 at 10:49 AM; no QC was performed afterwards J) Calibration performed on 2/11/2021 at 12:42 PM; no QC was performed afterwards K) Calibration factor adjustment on 7/8/2021 at 10:40 AM; no QC was performed afterwards 2. During the exit summation on 8/19/2021 at 3:20 PM, the Technical Consultant explained quality control drifts were the reason for the frequent QC adjustments; but offered no other explanation for the unacceptable quality control performance, after the adjustments were made. Additionally, the Technical Consultant stated he thought the testing personnel were running QC after he performed calibrations and calibration factor adjustments, however he had not remained in the lab to ensure they had. .
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) 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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on reviews of the calibration and calibration adjustment records for the Beckman Coulter AcT diff Hematology analyzer, reviews of the laboratory's Coulter AcT diff Procedure, and the calibration instructions in the Operator's Manual, a review of Quality Control (QC) records, and interviews with the Technical Consultant, the surveyor determined the laboratory failed to implement an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the quality of the analytic systems. These systemic failures were noted to occur since the previous survey on 10/9/2018. The findings include: 1. A review of calibration and calibration factor adjustment records for the Beckman Coulter AcT diff Hematology analyzer revealed the laboratory failed to implement quality assurance procedures to ensure: A) a full calibration including Reproducibility, Carryover and at least two levels of QC within acceptable limits was performed every six months as per the laboratory procedure. B) a full calibration was performed whenever critical components were replaced, as per the laboratory procedure and the manufacturer's instructions C) QC was run and within acceptable ranges each time a calibration was performed or calibration factor adjustments were made. (Refer to D5437.) 2. The surveyor further noted calibration factor adjustments were frequently made (twelve times in a two and a half year period) without investigating whether other factors were causing trends or bias in the QC data. A review of the manufacturer's instructions under Calibration Overview on Page 5-1 in the Beckman Coulter AcT diff Operator's Manual revealed, "...If recalibration appears necessary, but you have not replaced a component affecting calibration, do NOT recalibrate the instrument. 1. First, thoroughly clean your analyzer following the Clean the Baths procedure ... 2. Then reanalyze a new vial of control material. ...If results remain outside expected ranges, call your Beckman Coulter representative. ...". There was no evidence the Baths were cleaned, as per instructions, or Beckman Coulter was contacted to determine why the analyzer calibration was frequently drifting. 3. During the exit conference at 3:20 PM on 8/19/2019, these concerns were reviewed and discussed with the Technical Consultant. SURVEYOR ID# 32558 Licensure and Certification Surveyor