Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2206672	07/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
Smith Lake Family Care	6610 Curry Highway, Jasper, 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 reviews of the Hematology records, the "Customer Training Manual", and an interview with the Technical Consultant and Testing Personnel #1, the laboratory failed to perform and document calibrations on the Horiba ABx Micros E-60 Hematology analyzer as required by the manufacturer's instructions. The surveyor noted three of four 2021-2023 calibrations were missing documentation of repeatability/precision checks. The findings include: 1. A review of the Micros E-60 Hematology System Customer Training Manual under "Preparation for Calibration" on page 61 revealed, "...3) Perform a repeatability/precision by running a normal sample ten times ... Calculate the coefficient of variation". [The surveyor noted the last sentence was underlined.] 2. A review of the Horiba ABx Micros E-60 Hematology records revealed calibrations were performed on 9/1/2021, 2/5/2022, 10/28/2022, and 6/8/2023. However, on the first two calibrations there was no documentation of the ten repeatability/precision runs or an analysis of the data. 3. A review of the 6/8/2023 calibration revealed the laboratory had performed the ten repeatability/precision runs, however the coefficient of variation had not been

	calculated, as of the day of the survey. 4. During an interview on 7/27/2023 at 12:15 PM, the Technical Consultant and Testing Personnel #1 reviewed the calibration records, and confirmed the above findings. .
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on reviews of the Horiba ABx Micros E-60 Hematology Quality Control (QC) records, the "Customer Training Manual", and an interview with the Technical Consultant and Testing Personnel #1, the laboratory failed to implement a mechanism to track for shifts and trends over time in the Hematology QC. This was noted from the previous survey on 8/24/2021 to the day of the current survey on 7/27/2023. The findings include: 1. A review of the Hematology QC records revealed only the daily instrument printouts were retained. There was no evidence of Levy-Jennings (L-J) charts printed periodically or any other mechanism to track for shifts and trends over time in the Hematology QC, such as submission of QC data to an IQAP (Interlaboratory Quality Assurance Program). 2. A review of the Micros E-60 Hematology System Customer Training Manual revealed the instrument did have the capability to print L-J charts. The manual included instructions under "Review QC Result History" on pages 32-34. 3. During an interview on 7/27/2023 at 11:30 am, the Technical Consultant and Testing Personnel #1 confirmed the laboratory did not have a mechanism to track for shifts and trends over time in the Hematology QC. The laboratory did not print the L-J charts, and was not enrolled in an IQAP. SURVEYOR ID #32558 Licensure and Certification Surveyor