Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0915549	10/08/2020
Name of Provider or Supplier	**Street Address, City, State**	
East Alabama Family Practice	2214 Gateway Drive Suite C, Opelika, 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 Beckman Coulter AcT diff calibration and quality control records, and an interview with the Clinical Manager (also Testing Personnel #1), the surveyor determined the laboratory failed to follow the manufacturer's instructions to verify calibrations by running quality controls (QC) and perform/document the Carryover studies, for two out of five calibrations of the Hematology analyzer performed in 2018 - 2020. The findings include: 1. A review of calibration records for the Beckman Coulter AcT diff revealed the instrument was calibrated on 4/17/2018 at 10:27 AM. However, there was no documentation QC was run after the calibration. (Three levels of QC were only run in the morning 6:40 to 6:44 AM.) 2. A review of the 11/4/2019 AcT diff calibration revealed no documentation of Carryover studies. 3. A review of the Coulter AcT diff Operator's Guide, under the CALIBRATION section on page 5-16 revealed, "...16. Verify calibration by running 4C PLUS Cell Control. ...". The performance of Reproducibility and Carryover were also included in the calibration procedure. Carryover instructions were on page 5-7 with the notation," Carryover...Prints PASS or FAIL message for the carryover test.". 4. During an

	interview and review of the records on 10/8/2020 at 12:00 PM, the Clinical Manager reviewed and confirmed the above noted findings. The surveyor then asked if any patient CBC's (Complete Blood Counts) were performed after the 4/17/2018 calibration. At 12:25 PM, the manager stated five patient CBC's were run after 10:27 AM on that date. .
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the 2018-2020 Beckman Coulter AcT diff quality control records (QC), and an interview with the Clinical Manager (also Testing Personnel #1), the surveyor determined the laboratory failed to follow the manufacturer's instructions to enter the lot number (#) and expiration when entering new cell control information. The laboratory failed to document the correct lot number and expiration date for over 21 months from 9/10/2018 to 6/23/2020. The findings include: 1. A review of the daily Hematology QC printouts revealed the same QC lot #'s: 69900 (Low), 79900 (Normal), and 89900 (High), and the same expiration date, 9/10/2018 were documented on the records for over 21 months from 9/10/2018 to 6/23/2020. 2. A comparison of the acceptable ranges on the QC records each day with the values on the Coulter QC assay sheets in use for that same period revealed the correct values were in use. Only the lot number and expiration dates were incorrect. 3. A review of the Coulter AcT diff Operator's Guide, under the CELL CONTROL "ENTERING CELL CONTROL INFORMATION", Section 2 on page 2-3 revealed, "...5. Select the cell control level (L, N, or H) by touching the level indicator. ... [The surveyor also noted the option of selecting "A"for "all", however the instructions specified "Not for use when entering the lot number or expiration date.".] ...6. Enter the lot number ... ... 7. Enter the expiration ... 4. During an interview on 10/8/2020 at 1:10 PM, the Clinical Manager stated she noticed the wrong lot numbers and the expiration date (9/10/2018) when she entered the new control information on 6/24/2020. The Manager then reviewed the Operator's Manual with the surveyor, and stated the previous manager had failed to follow the manufacturer's instructions. The previous manager had entered the correct values, but had failed to use the option that allowed entry of the lot #/expiration. .
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the 2018-2020 Beckman Coulter AcT diff Hematology analyzer quality control (QC) records and an interview with the Clinical Manager (also Testing Personnel #1), the surveyor determined the laboratory failed to ensure at least two

	levels of Hematology QC were within acceptable limits before patient testing began. This was noted on one day of patient CBC (Complete Blood Count) testing in April 2019. The findings include: 1. A review of the daily Hematology QC instrument printouts revealed on 9/6/2019 only the Low QC was acceptable. The surveyor noted several parameters on the Normal and High QC were outside acceptable ranges. 2. During an interview and review of the QC records on 10/8/2020 at 1:15 PM, the Clinical Manager confirmed the above noted findings. When asked if any patient testing was performed on 9/6/2019, the Manager stated 11 patient CBC's were run. SURVEYOR ID#32558 Licensure and Certification Surveyor