Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D1082251	12/15/2020
Name of Provider or Supplier	**Street Address, City, State**	
Auburn Family Medicine	665 North Dean Road, Auburn, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a review of the proficiency testing records and an interview with Testing Personnel (TP) #5, the surveyor determined the laboratory failed to ensure proficiency testing was rotated among all testing personnel who routinely perform moderate complexity testing of Complete Blood Counts (CBCs). This affected seven of seven testing events in 2018 - 2020, reviewed by the surveyor. The findings include: 1. A review of seven proficiency testing events in 2018 - 2020 revealed TP #5 signed the attestation statements for four testing events. TP #7 signed one attestation statement, and a former employee signed two. Although only three employees participated in proficiency testing for these seven events, the laboratory listed nine testing personnel who were trained and found competent to test CBC samples in 2018 - 2020. 2. During an interview on 12/15/2020 at 12:23 PM, TP #5 stated the various testing personnel perform the CBC testing for the provider, of which they accompany for each day. TP #5 clarified this statement by saying each of the testing personnel performs CBCs and had opportunity to perform proficiency testing, but had not participated in proficiency testing. TP #5 further stated the laboratory could better rotate the testing of proficiency testing samples.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at

	least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the Hematology maintenance records, a review of the Beckman Coulter DxH 520 Instructions of Use Manual, and an interview with Testing Personnel # 5 the laboratory failed to performed maintenance as recommended by the manufacturer. This was noted on seven of eight months for Performing a Bleach Cycle and six of eight months for Cleaning the White Blood Cell (WBC) Bath Filter, reviewed after the analyzer was installed in April, 2020. The findings include: 1. A review of the Hematology maintenance records revealed monthly maintenance was not documented April - September and November 2020 for Performing a Bleach Cycle for the Beckman Coulter DxH 520 analyzer. Also, maintenance was not documented April - September 2020 for Cleaning the WBC Bath Filter for the Beckman Coulter DxH 520 analyzer. 2. A review of the Beckman Coulter DxH 520 Instructions of Use Manual revealed in Chapter 12 (page 12-1) "Procedure - Performing a Bleach Cycle.... Frequency - Every 1,000 cycles or monthly, whichever comes first" and "Procedure - Cleaning the WBC Bath Filter...Frequency - Monthly". 3. During an interview on 12/15/2020 at 12:40 PM, Testing Personnel # 5 confirmed Cleaning the WBC Bath Filter monthly did not start until October 2020 and Performing a Bleach Cycle was being performed every 1,000 cycle instead of monthly.
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 Hematology calibration records for 2018 - 2020 and an interview with Testing Personnel # 5, the laboratory failed to perform calibrations on the AcT diff at least once every six months. This affected the calibration period between 9/12/18 - 8/4/2019. The findings include: 1. A review of the Hematology calibration records revealed the AcT diff was calibrated on 09/12/2018 and not again until 08/04/2019, almost one year later. 2. During an interview on 12/15/2020 at 11:05 AM, Testing Personnel # 5 confirmed she noticed on 08/01/2019 the calibration for March 2019 was not performed.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least

	annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of the personnel records and an interview with Testing Personnel (TP) #5, the surveyor determined the Technical Consultant failed to assess the competency of TP #9 in 2018. TP #9 was employed in the laboratory, performing moderate complexity testing, for greater than one year. This affected one of nine testing personnel, who perform Complete Blood Counts (CBCs). The findings include: 1. A review of the CMS form #209 (Laboratory Personnel Record) from the previous survey on 3/29/2018 revealed TP #9 had previously qualified as a testing personnel of moderate-complexity testing (CBC testing). The laboratory's personnel records failed to include a competency assessment for TP #9 for 2018. 2. During an interview on 12/15/2020 at 10:45 AM, TP #5, the Licensed Practical Nurse supervising the laboratory, reviewed the personnel manual and confirmed there was no annual competency assessment in 2018 for TP #9.