Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0300309	12/04/2018
Name of Provider or Supplier	**Street Address, City, State**	
Cahaba Family Medicine	2508 Highway 31 S, Pelham, 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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records, including the manufacturer's assay information sheets and QC instrument data logs, and an interview with the technical consultant, the surveyor determined the laboratory used expired quality control material for daily QC performance. The use of expired quality control occurred twice from April 2017 - June 2018. The findings include: 1. A review of the QC records (instrument data logs) revealed QC lot numbers 068700, 078700 and 088700 for low, normal and high controls, respectively, expired on 4/24/17. These lot numbers were used for QC testing on 4/25, 4/26 and 4/27, beyond the date of expiration. 2. A review of the QC records (instrument data logs) revealed QC lot numbers 068400, 078400 and 088400 expired on 2/26/18. However the QC records indicated the QC material (low, normal and high) were used to perform QC testing on 2/27/18, after the date of expiration. 3. The surveyor confirmed the expiration dates of the QC material by reviewing the manufacturer's assay information for these QC lot numbers. 4. In interviews on 12/04/18 at 11:31 AM and 12:45 PM, the technical consultant reviewed the QC records and confirmed the use of expired quality control material, based on the lot numbers, expiration dates and dates of QC testing noted on the data logs.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with

	at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of quality control records (including the background checks) for the Beckman Coulter Act Diff 2, an internet review of the operators' manual, and an interview with the technical consultant, the surveyor determined the laboratory failed to ensure the background checks were within acceptable limits, prior to performing quality control and patient testing for Complete Blood Counts (CBCs). This affected four days of patient testing from February 2017 - July 2018. The findings include: 1. A review of the quality control records, which included the background checks, for the Act Diff 2 revealed the following failures: a) The background check for platelets failed on 2/13/2017. The background was repeated, however failed the repeat testing. b) On 4/24/2017, the background check for platelets failed. The laboratory did not repeat the background check. c) On 7/16/2018, the background check for platelets failed. The laboratory failed to repeat this function check. d) On 7/25/2018, the background check for hemoglobin failed and was not repeated. 2. An online review of the operators' manual for the Act Diff 2 revealed the following: "ROUTINE PROCEDURES 1.1 STARTUP... 2 The instrument performs the startup routine and reports a PASS or FAIL for the WBC (White Blood Cell Count), RBC (Red Blood Cell Count), Hgb (Hemoglobin) and Plt (Platelets) parameters." The troubleshooting section of the manual included possible causes of failed background checks, including contaminated diluents, baths, bubbles in the baths, blood in the aspiration paths, and sometimes an electrical interference. 3. In an interview on 12/04/2018 at 11:31 AM, the surveyor inquired of the procedure when a background failed and did not pass. The technical consultant stated failed background checks were usually repeated. The technical consultant reviewed the records and confirmed the backgrounds did fail on the above mentioned dates and were not repeated (no documentation of repeats). 4. Patient testing continued, though the background counts exceeded acceptable limits.
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 a review of quality control records and an interview with the technical consultant, the surveyor determined the laboratory failed to implement a procedure to monitor the analytic testing process for errors which may occur over time. These errors may be noted by occurrences of shifts or trends in quality control testing. This affected the survey review period, February 2017 - December 2018 (the 4th day). The findings include: 1. The laboratory's quality control records failed to include any

	graphs or charts (i.e. Levy - Jennings) to indicate the performance of quality control testing over a period of time. There were not records of peer group comparisons, either. 2. In an interview on 12/04/2018 at 12:45 PM, the surveyor asked the technical consultant how the laboratory monitored for shifts, trends, or errors which may occur in the testing system over a period of time. When asked if the laboratory printed graphs or charts, which may be reviewed for shifts or trends, the technical consultant replied the laboratory did not, but confirmed the instrument provided the capability. The technical consultant further stated the laboratory enrolled previously in peer group comparison studies for the instrument, but had not in a long time.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of new instrument installation and validation records and an interview with the technical consultant, the surveyor determined the laboratory director failed to ensure the newly installed Beckman Coulter Act Diff 2 performed according to manufacturer's specifications, by verifying the accuracy, precision and reportable range of the instrument. This affected one of one new instrument installations, since the previous survey on 1/25/17. The findings include: 1. At 12:45 PM on 12/04/18, the technical consultant informed the surveyor the laboratory had installed a new Beckman Coulter Act Diff 2, since the previous survey (installed in October of 2018). The laboratory previously used an older model of the Act Diff 2. 2. A review of the installation and validation records for Act Diff 2, installed October 20, 2018, revealed a calibration (including reproducibility and carryover) and raw data of a linearity study (reportable range study). However, there was no evidence the laboratory director had reviewed and evaluated the data to determine accuracy, precision and reportable range. 3. At 1:07 PM, the surveyor asked if any of the data had been reviewed for verification of performance specifications (accuracy, precision and reportable range). The surveyor asked if the laboratory director had seen the installation and validation data. The technical consultant stated the laboratory director had not reviewed the records. There was no laboratory director signature on the records to note his review and evaluation and acceptance of the data as evidence of adequate performance of the instrument.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the

	type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of personnel records and an interview with one of two technical consultants, the surveyor determined the laboratory director failed to ensure testing personnel (TP) #2 received the appropriate training for the performance of CBCs (Complete Blood Counts), prior to testing patient specimens. This affected one of three testing personnel, who performed moderate complexity laboratory testing. The findings include: 1. A review of the personnel records revealed no documentation of training for TP #2, who was identified on the CMS #209 Personnel Form as new testing personnel, since the previous survey (1/25/2017). 2. In an interview on 12/04 /18 at 10:00 AM, the technical consultant stated TP #2's date of hire was in July of 2018. In the personnel record for TP #2 was a safety training checklist, dated 7/09/18. At this time, the technical consultant confirmed TP #2 performed CBC testing on patient specimens. When asked if the laboratory had documentation of TP #2's training, the technical consultant reviewed the file and stated she must not have completed the training checklist. Patricia Watson, BS, MT (ASCP) Licensure and Certification Supervisor