Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0873955	12/04/2025
Name of Provider or Supplier	**Street Address, City, State**	
Montgomery Family Medicine Pc	8190 Seaton Place, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observations during the laboratory tour, a lack of the Room Temperature (RT) and Humidity records for the Beckman Coulter (BC) DxI 600 analyzer, a review of the manufacturer's environmental requirements, and an interview with Technical Consultant (TC), who is also the Testing Personnel 1 (TP1), the laboratory failed to implement a mechanism to ensure the instrument was operated within the manufacturer's required environmental parameters for 25 of the 25 months reviewed in 2023-2025. The findings include: 1) On 12-04-2025 at 11:18 AM during a tour of the room where the BC DxI 600 analyzer operated, the surveyor observed no temperature or humidity monitoring device. 2) A review of the BC DxI Reference Manual revealed the following operating environment requirements on page A-4. A) Temperature Operational: 64F to 86F (18C to 30C) B) Humidity: RH [Relative Humidity] (non-condensing) Operational: 20-85% 3) During the exit conference on 12-04-2025 at 2:33 PM, TC/TP1 confirmed the laboratory had not implemented procedures to ensure the BC DxI 600 analyzer was operated within the environmental parameters required by the manufacturer since the previous survey.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observations during the initial tour, reviews of the SYSMEX EIGHTCHEK 3WP XTRA Hematology control package insert, the Beckman Coulter (BC) Bicarbonate Calibrator package insert, and an interview with the Technical Consultant (TC), also the Testing Personnel 1 (TP1), the testing personnel failed to write the new expiration dates on the Hematology Quality Control (QC) and Bicarbonate Calibrator bottles upon opening. This was noted on three out of the three vials of QC and two out of the two bottles of Bicarbonate calibrators currently in use. The findings include: 1. During the laboratory tour on 12-04-2025 at approximately 9:19 AM, the surveyor observed the three levels of Hematology QC and the two levels of Bicarbonate Calibrators in use had no updated expiration dates written on the vials upon opening. 2. A review of the SYSMEX EIGHTCHEK 3WP XTRA Hematology control package insert revealed the following: A) Storage and shelf life after opening "Open and recapped vials and vials whose caps have been pierced will retain stability for 14 days ..." 3. A review of the BC Bicarbonate Calibrator package insert revealed the following: B) Calibrator Storage and Stability: "Opened bottles are stable up to 30 days... (tightly capped immediately after each use and stored at 15 to 25C)." 4. The TC confirmed the above findings during the exit conference on 12-04-2025 at 2:33 PM.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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 observations during the laboratory tour, a review of the 2023-2025 Beckman Coulter (BC) DxI 600 calibration logs, and an interview with the Technical Consultant (TC), who is also the Testing Personnel 1 (TP1), the laboratory failed to ensure testing personnel utilized in-date calibrators when calibrating Chemistry and Endocrinology analytes before patient testing for 11 out of the 25 months reviewed from 2023-2025. The findings include: 1. Direct observation of the refrigerated calibrators during the laboratory tour at approximately 9:28 AM revealed nine expired Chemistry and Endocrinology calibrators, as follows: A) Lyophilized Chemistry Calibrator 1 and 2, Lot 6102K21, Expiration date 5-31-2025 B) Free Triiodothyronine (FT3), Lot 489932, Expiration Date 7-16-2025 C) Free Thyroxine (FRT4), Lot 338395, Expiration Date 10-31-2025 D) Folate (FOLW), Lot 439771, Expiration Date 12-31-2024 and Lot 440440, Expiration Date 5-31-2025 E) 3rd Generation Thyroid Stimulating Hormone (TSH3), Lot 440145, Expiration Date 10-31-2025 F) Prostate-Specific Antigen (PSA) Hybritech (PSA-Hyb), Lot 439984, Expiration Date 8-31-2025, ands Lot 440303, Expiration Date 10-31-2025 G) Testosterone (Testo), Lot

	440047, Expiration Date 8-31-2025 H) Vitamin B12 (VitB12), Lot 439541, Expiration Date 4-30-2025 I) Vitamin D (VitD), Lot 440422, Expiration Date 8-31-2025 2. A review of the BC DxI 600 calibration logs revealed the expired calibrators were used from December 31, 2024 through December 4, 2025. 3. After a review of the laboratory information system testing history records, TC/TP1 stated approximately 30,000 patient tests were performed during the 11 months when expired calibrators were in use. 4. During the exit conference on 11-04-2025 at 2:33 PM, the TC/TP1 confirmed the above findings.
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. This STANDARD is not met as evidenced by: Based on a review of Quality Assurance (QA) records and an interview with Technical Consultant (TC), who is also the Testing Personnel 1 (TP1), the laboratory failed to implement a mechanism to ensure the quality of the analytical systems. Failures were noted to occur from the date of the previous survey, 10-18-2023 until the current survey of 12-04-2025. The findings include: 1. A review of QA records revealed the QA policy and procedure in the laboratory failed to identify and correct the following problems in the analytical system. A) Failure to implement a mechanism to ensure the Beckman Coulter DxI 600 analyzer was operated within the manufacturer's required environmental parameters. (Refer to D5413) B) Failure to write the new expiration date when the Quality Control and Calibrator materials were opened according to manufacturer's specifications. (Refer to D5415) C) Failure to utilize in-date Calibrators prior to patient testing. (Refer to D5417) 2. During the exit conference on 11-04-2025 at 2:33 PM, the TC/TP1 confirmed the above findings.