Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0701549	10/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
Walton Family Medicine Pc	521 Great Oaks Drive, Monroe, GA	

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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on October 24, 2024. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) and maintenance documents review, the laboratory director failed to sign off on ALL quality assessment activities on a monthly basis as required by Clinical Laboratory Improvement Amendments (CLIA) from November 2022 to day of survey 10/24/2024. Findings: 1. A review of the laboratory's (QA) activities revealed the technical consultant (TC), who is also the lab director, did not review and sign all monthly Quality Assessment(QA) activities including; daily maintenance and QC reviews for the Horiba Micros 360 Hematology analyzer. Eye wash, incubator, humidity, refrigerator and room temperature logs from November 2022 through day of survey 10/24/2024 were not reviewed by the Laboratory Director. The reviews were done by TP#2 (CMS 209) who was not qualified to do so. 2. An interview with the nurse supervisor, on 10/24/2024, at approximately 12:15 PM, in the review room, confirmed all (QA) activities were monitored and signed off by TP#2 CMS 209 who was not qualified to act as (TC) from November 2022 through day of survey 10/24/2024.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on documents review and interview with the nurse manager, the Lab Director (LD) failed to ensure that ALL Quality Assurance (QA) guidelines were followed to identify and fix problems in the laboratory from November 2022 to 10/24/2024 as required by Clinical Laboratory Improvement Amendments (CLIA). Findings: 1. Quality Assurance (QA) document review revealed the Lab Director, who is also the Technical Consultant (TC), did NOT review and sign off on monthly Quality Assesment (QA) activities from November 2022 to 10/24/2024. 2. An interview with the nurse manager, in the review room on 10/24/2024 at approximately 12:35 PM, confirmed the Lab Director failed to ensure proper oversight of the laboratory's (QA) activities from November 2022 through day of survey 10/24/2024.