

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D2255252	<b>(X3) Date Survey Completed</b>  06/22/2023
<b>Name of Provider or Supplier</b>  Family Care Habersham	<b>Street Address, City, State</b>  790 Old Historic Us 441, Demorest, GA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on June 22, 2023. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
<b>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on API ( American Proficiency Institute ) Proficiency Test (PT) documents review and staff interviews, the laboratory failed to enroll in a CMS approved PT program in 2022 and 2023 in the Specialty of Chemistry. Findings: 1. Review of (API) Proficiency Testing (PT) documents revealed the laboratory failed to enroll in PT testing during in the third(3) quarter of 2022, first(1) and second(2) quarters of 2023 on the Abbott ISTAT 1 Chemistry analyzer. 2. The clinic is using the Moderately Complexity BLUE CHEM 8+ ISTAT Cartridge which requires PT enrollment. 3. An interview with the lab manager (TP #5 CMS 209) in the review room at approximately 12:30 PM on 06/22/2023, confirmed no enrollment in a CMS approved PT program for the Abbott ISTAT Chemistry analyzer in 2022 and 2023.</p>
<b>D6021</b>	<b>LABORATORY DIRECTOR RESPONSIBILITIES</b>

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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on document review and interview with the Laboratory Manager, the Lab Director (LD) failed to ensure that all Quality Assurance (QA) guidelines were followed to identify and fix problems in the laboratory in 2022 and 2023 as required by Clinical Laboratory Improvement Amendments (CLIA). Findings: 1. Monthly QA document review revealed the Lab Director, who is also the Technical Consultant (TC), did not ensure the laboratory's (API) Proficiency Testing (PT) enrollment for the Abbott ISTAT 1 Chemistry analyzer based on the Cartridge used in 2022 and 2023. 2. An interview with the Laboratory Manager (TP#5) CMS 209, in the review room, on 06/22/2023, at approximately 12:40 PM, confirmed the Lab Director failed to ensure proper oversight of the laboratory's PT enrollment in 2022 and 2023.