

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0983961	(X3) Date Survey Completed 05/26/2021
Name of Provider or Supplier Cynthia Chambless Md	Street Address, City, State 6501 Peake Road Building 200, Macon, 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 May 26, 2021. Condition and Standard level Citations were found. 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:
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES 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 review of the American Association of Bioanalysts (AAB) Proficiency Testing (PT) provider, for the year 2020, the laboratory failed to enroll in a PT program for Subspecialist of Hematology (CBC). The laboratory was still testing patient samples. Reference: D6015</p>
D6015	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)</p> <p>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</p>

director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on review of the American Association of Bioanalysts (AAB) Proficiency Testing (PT) provider, for the year 2020, the Laboratory Director (LD) failed to confirm that the laboratory was enrolled in a PT program for Specialty of Hematology (CBC), for the year 2020 The laboratory was still testing patient samples. Findings: 1. Based on review of the AAB PT documents, the laboratory failed to participate for all three events in 2020 for the Specialty of Hematology. 2. Staff interview with the LD and staff #3(CMS form 209) on May 26th, 2021, at approximately 5pm in the back hall, and with Staff #3 on the phone on May 26th, 2021 at approximately 4:45pm, confirmed that the AAB PT for the year 2020 was not ordered, by the deadline.