

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0978047	(X3) Date Survey Completed 04/27/2021
Name of Provider or Supplier West Atlanta Internal Medicine Pc	Street Address, City, State 6128 Prestley Mill Road Suite G, Douglasville, 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 April 27, 2021. 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:
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on Quality Assurance (QA) document review and interviews with the office manager and owner, the laboratory director failed to document all general laboratory systems QA activities as required. Findings include: 1. QA documents review revealed there were no monthly or quarterly maintenance and QA documentations available, reviewed and signed by the laboratory director who also acts as the Technical Consultant (TC) from May 2019 and April 2021. 2. Interviews with the office manager and owner(who is also the laboratory director and Technical Consultant) in the break room on 05/27/2021 at approximately 12:30 p.m. confirmed lack of consistent QA oversight by the laboratory director for the aforementioned period.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory</p>

must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on document review and interviews with both Laboratory director and office manager, the laboratory failed to provide laboratory maintenance records from May 2019 to April 2021. Findings include: 1.) Document review revealed no laboratory maintenance record logs for Room Temperature and Relative Humidity from May 2019 to April 2021. 2.) No consistent daily, weekly and monthly maintenance logs for the Horiba Micros 60 Hematology analyzer from May 2019 to April 2021. 3.) Interviews with the Laboratory director(Owner) and office manager at approximately 12:45 pm on 04/27/2021 in the break room confirmed the absence of the aforementioned documents from May 2019 to April 2021 at the time of Survey.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

After a review of the procedure manual, personnel records and an interview with the laboratory director, it was determined that the laboratory did not have a comprehensive competency assessment policy with CLIA six(6) standards for its testing personnel specific to the specialty of Hematology. Findings include: 1.) Testing Personnel (TP) record review revealed that competency assessment was performed in 2019 and 2020. However, the policy did not clearly contain the six (6) CLIA criteria for personnel competency assessment. 2.) The laboratory director and office manager confirmed after an interview on 04/27/2021 at approximately 12:50 pm, in the break room that the laboratory competency assessment policy needs upgrading with the current six (6) CLIA standard criteria.