

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0262290	(X3) Date Survey Completed 01/18/2022
Name of Provider or Supplier Adventhealth Medical Group Family Medicine	Street Address, City, State 109 Hospital Drive, Calhoun, 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 January 18, 2022. 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:
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: A review of personnel records and staff interview confirmed that the laboratory failed to establish a written policy to assess the six criteria's for employee competency for the specialty of hematology. The findings include: 1. The laboratory failed to have a written competency policy and procedure that include the six required criteria for testing personnel for years 2020 and 2021. 2. An annual competency assessment was not performed for any of the staff for 2020 or 2021 in the specialty of hematology. 3. An interview with the Laboratory Manager and the new Technical Consultant on January 18, 2022, at approximately 4:00 PM, confirmed that the laboratory did not have a policy to assess the required six competency criteria for the testing personnel in the laboratory.</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when</p>

appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on review of the laboratory procedure manual and interview with Practice Manager, the laboratory failed to establish written instructions for sending specimens to an outside reference laboratory for testing. The findings include: 1. The laboratory's procedure manual did not include a written policy and procedure (to include collection, preservation, storage, transport, testing schedule times, and how to obtain additional assistance) for staff to follow when sending specimens to reference laboratories (Gordon Hospital, LabCorp, and Quest Diagnostics). 2. During an interview on January 18, 2022 at 3:30 PM with the Practice Manager and the new Technical Consultant, confirmed that the laboratory did not have a written policy and procedure for staff to follow when sending specimens to a reference laboratory.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 maintenance log review and staff interview, the laboratory failed to monitor and document room temperature and humidity as required by the manufacturer. Findings include: 1. Maintenance log review revealed the laboratory failed to monitor room temperature and humidity in the laboratory as required by the manufacturer of the Sysmex analyzer for (January- December 2020). 2. During an interview with the Practice Manager and the new Technical Consultant on January 18, 2022, in an office across from the laboratory, confirmed there was no room temperature and humidity monitoring or documentation for 2020.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on review of the laboratory policy and procedure manual (SOP) and staff

interview, the laboratory director (LD) failed to specify, in writing, the duties and responsibilities of each person engaged in the performance of the pre-analytic, analytic, and post-analytic phases of laboratory testing. Findings include: 1. SOP review revealed the LD failed to specify, in writing, the duties and responsibilities of each person engaged in the performance of all phases of laboratory testing. 2. During an interview with the Practice Manager and the new Technical Consultant, on January 18, 2022, at approximately 2:30 PM, in an office across from the laboratory, confirmed the SOP did not contain the duties and responsibilities for all personnel engaged in the performance of clinical laboratory testing.

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:
Based on review of the laboratory's testing personnel competency assessment checklist and staff interview, the laboratory failed to ensure the competency assessment policy and procedure, for testing performed in the speciality of Hematology, met the 6 required criteria. The Findings include: 1. Laboratory document review revealed the laboratory was performing competency, but their competency assessment checklist did not include the 6 required criteria for the speciality of Hematology. 2. During an interview with Practice Manager and the new Technical Consultant on January 18, 2022, at approximately 2:20 PM, confirmed that the laboratory was performing competency on the testing personnel, but it did not follow the 6 required criteria for the specialty of Hematology.