

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1067271	(X3) Date Survey Completed 11/20/2025
Name of Provider or Supplier Ocmulgee Physicians Laboratory	Street Address, City, State 446 Poplar Street, 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 November 20, 2025. 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:
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>(d)(3)(i) Each quantitative procedure, include two control materials of different concentrations;</p> <p>This STANDARD is not met as evidenced by: A review of 2023 - 2025 Quality Control Records confirmed that the laboratory failed to include the required control levels for all test procedures when processing test samples as required by CLIA Regulation 493.1256(d)(3)(i). THE FINDINGS INCLUDE: 1. A review of 2023 - 2025 Quality Control Records revealed the lack of quality control documentation for the Erythrocyte Sedimentation Rate (ESR) testing by the Westergren method. 2. An interview with testing personnel confirmed that quality controls were not performed for ESR testing. 3. A review of the 2023 - 2025 Quality Control records revealed that quality controls for the Polymerase Chain Reaction (PCR) testing were performed once per week, as opposed to running with each testing run as required. 4. A review of the Quality Controls SOP confirmed that an Individualized Quality Control Plan (IQCP), to support the deviation from regulatory requirements, was not established. 6. An exit interview, with Laboratory Staff, on November 20, 2025, at 2:30pm, in the Lab Office, confirmed that the laboratory failed to include the required control levels for all test procedures when processing test samples.</p>
D6020	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p>

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:

A review of the 2023 - 2025 Quality Control Records and the 2023 - 2025 Quality Assurance Records confirmed that the Laboratory Director failed to establish and to maintain quality control and quality assessment programs to assure the quality of laboratory services provided. THE FINDINGS INCLUDE: 1. A review of the 2023 - 2025 Quality Assurance Records confirmed that the Laboratory Director had not performed the required quality assurance oversight of the laboratory quality control and quality assessment programs. 2. An exit interview, with Laboratory Staff, on November 20, 2025, at 2:30pm, in the Lab Office confirmed that the Laboratory Director failed to establish and to maintain quality control and quality assessment programs to assure the quality of laboratory services provided.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(a)(b)

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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

A review of the 2023 - 2025 Personnel Records confirmed that Laboratory Director failed to complete annual competencies for the General Supervisor and the Technical Supervisor for years 2023 - 2025 or establish the required letters of Delegation for shared duties. THE FINDINGS INCLUDE: 1. A review of the 2023- 2025 Personnel Records revealed that the annual competencies for the General Supervisor and the Technical Supervisor were not completed in years 2023 - 2025. 2. A review of the 2023 - 2025 Quality Assurance Records confirmed that Testing Personnel performed the quality assurance programs. The required Letters of Delegation from the Laboratory Director was not available on the date of survey 3. An exit interview, with Laboratory Staff, on November 20, 2025, at 2:30pm, in the Lab Office confirmed that the Laboratory Director failed to complete annual competencies for the General Supervisor and the Technical Supervisor for years 2023 - 2025 or establish the required letters of Delegation for shared duties.