Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0908135	01/20/2026
Name of Provider or Supplier	**Street Address, City, State**	
Crawford Family Medicine	106 Mccrary Ave Po Box 1010, Roberta, 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 20, 2026. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1s through 42 CFR 493.1780. The following deficiencies were cited:
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: A tour of the laboratory confirmed that specimens were not labeled in a manner to ensure positive identification and optimum integrity of patients' specimens. THE FINDINGS INCLUDE: 1. A review of collected specimens, during the laboratory tour, revealed that specimens were not labeled with first and last name, date of birth, unique identifier, collection date and time, or collector's identification. 2. An exit interview, with Testing Personnel and Laboratory Director, on January 20, 2026, at 12: 00pm, in the laboratory confirmed that specimens were not labeled in a manner to ensure positive identification and optimum integrity of patients' specimens.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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: A review of 2024 - 2026 Temperature Records confirmed that the laboratory failed to monitor and document the testing environment conditions, as required by the manufacturer, to ensure accurate and reliable test system operations. THE FINDINGS INCLUDE: 1. A review of the manufacturer User Manuals revealed the following: a. The Abbott Afinion 2 User Manual requires the following testing environment: Temperatures of 15C to 32C (59F to 89F) and Humidity requirements of 10-80%, non- condensing. b. The Vulcon Technology Variseal Centrifuge User Manual requires the followig testing environment: Temperature of 2C - 35C and humidty monitoring c. The AO Scientific Instrument One Fifty Microscope User Manual requires the following operating environment: 5C to 40C (41F to 104F) and humidity monitoring 2. A review of 2024 - 2026 temperature records revealed that there were no records documenting room temperature or room humidity monitoring. 3. An exit interview, with testing personnel and the Laboratory Director, on January 20, 2026, at 12:00pm in the laboratory, confirmed that the laboratory failed to monitor or document the testing environment conditions as required by the manufacturer for accurate and reliable test system operations.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: A review of all 2024 - 2026 laboratory records confirmed that the laboratory failed to perform or document maintenance as required by the manufacturer. THE FINDINGS INCLUDE: 1. A review of the 2024 - 2026 laboratory records confirmed that there was no documentation of maintenance for the Vulcon Technologies Variseal Centrifuge and the AO Scientific Instrument One Fifty Microscope, as required by the manufacturer. 2. An exit interview, with testing personnel and Laboratory Director, on January 20, 2026, at 12:00pm, in the laboratory, confirmed that the laboratory failed to perform or document maintenance as required by the manufacturer.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions 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 all 2024 - 2026 Laboratory Records confirmed that the Laboratory Director failed to conduct proper oversight of all laboratory operations. Reference D5203, D5413, D5429, D6030, D6031, and D6070
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: A review of 2024 - 2026 personnel records confirmed that the Laboratory Director failed to perform competencies as required. THE FINDINGS INCLUDE: 1. A review of 2024 - 2026 Personnel Records confirmed the personnel competency for Testing Personnel #1 (see CMS-209 personnel form) was not completed. 2. An interview with Testing Personnel #1 confirmed that a competency was not performed by the Laboratory Director/ Technical Consultant. 3. An exit interview, with Testing Personnel and Laboratory Director, on January 20, 2026, at 12:00pm, in the laboratory confirmed that the Laboratory Director failed to ensure testing personnel competencies were completed.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: A review of the current Laboratory Procedure Manual confirmed that the Laboratory Director failed to provide revised and the additional required procedure manuals for testing personnel. THE FINDINGS INCLUDE: 1. A review of the current Laboratory Procedure Manual confirmed that the test list, in the procedure manual, did not correlate with the tests currently performed in the laboratory. 2. A review of the current Laboratory Procedure Manual revealed: a. Test procedures contained only list of tests. b. There were no step-by-step instructions in the performance, assessment, or documention of quality control results. c. The procedure did not meet the regulated format as required by CLIA Regulation 493.1251(b) Procedure Format. 3. A review of the laboratory procedure manual revealed that procedures were outdated, with procedures last reviewed in 2014. 4. A review of the procedure manual revealed that the following required procedures were not available on the date of survey: Down Time, Safety, Personnel, Maintenance, Temperature, Specimen Handling & Storage, Reagent Handling & Storage, Critical Results Values Assessment & Reporting, Normal Results procedures. 5. An exit interview, with testing personnel and the Laboratory Director, on January 20, 2026, at 12:00pm, in the laboratory confirmed

	that the Laboratory Director failed to provide revised and the additional required procedure manuals for Testing Personnel.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) (b) Each individual performing moderate complexity testing must-- (b)(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results; This STANDARD is not met as evidenced by: A review of the Proficiency Testing Procedure, in the current laboratory procedure manual, confirmed that laboratory staff failed to follow the proficiency testing procedure. THE FINDINGS INCLUDE: 1. A review of the Proficiency Procedure revealed the following: "Crawford Family Medicine is enrolled in an HCFA-approved proficiency testing program." 2. Laboratory document review revealed that there was no proof of enrollment into an approved proficiency testing program. 3. An interview with testing personnel confirmed that the laboratory performed peer-to-peer testing reviews, to comply with proficiency testing requirements rather than enrollment in an approved proficiency testing program, as stated in the proficiency procedure. 4. An exit interview, with testing personnel and the Laboratory Director, on January 20, 2025, at 12:00pm, in the laboratory confirmed that laboratory staff failed to follow the proficency procedure.