Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0952100	08/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
Family Physicians Of Evans	465 North Belair Road, Suite 1c, Evans, 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 August 14, 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:
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: A review of current Procedure Manual (SOP) confirmed that the SOP failed to contain step by step procedures for ALL technical testing operations that occur in the laboratory. THE FINDINGS INCLUDE: 1. A review of the laboratory SOP's revealed that ALL tests, assays, and examinations performed by the laboratory were not included in the Standard Operating Procedures. 2. A review of the laboratory SOP confirmed various log sheets for recording maintenance and temperatures were contained in the SOP however actual written step-by-step procedures for ALL laboratory operations were not available. 3. A review of the Laboraotory SOP revealed there were no Down Time, Maintenance, Temperature Monitoring, Specimen Handling & Storage, Quality Assurance or Quality Control Procedures. 4. An exit interview, with the Technical Consultant and the Testing Personnel, on August 14, 2025, at 2:00pm, confirmed that the SOP manual did not contain step by step procedures for ALL laboratory testing operations that occur in the laboratory.
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 tour of the laboratory environment and a review of the 2023 - 2025 Temperature Logs confirmed that reagents and collection tubes were not stored as required by the manufacturer. THE FINDINGS INCLUDE: 1. A review of the Freezer Temperature Reagent Storage Logsheet confirmed a temperature range of -20C - 0C. 2. A review of the BIO-RAD LiquiChek Immunoassay Plus Controls revealed a storage requirement of -70C - -20C however the BIO-RAD LiquiChek Immunoassay Plus Controls were stored in the Reagent Storage Freezer with a temperature range of -20C - 0C. 3. A review of the drawing room, used for storage of supplies, confirmed the temperature of the drawing room was not monitored. The following reagent and supplies were discovered: a. BD VACUTAINERS with temperature storage requirements of 4C - 25C; 4. An exit interview, with the Technical Consultant and the Testing Personnel, on August 14, 2025, at 2:00pm, confirmed that reagents were not stored as required by the manufacturer.
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 tour of the laboratory confirmed that the laboratory failed to perform the preventive maintenance as required by the manufacturer. THE FINDINGS INCLUDE: 1. A review of the Clinical Pathology Laboratory's Centrifuge maintenance record and maintenance sticker revealed that the biannual speed calibration expired on 02/23 /2025. 2. An interview with the Technical Consultant confirmed that the speed calibration had not been performed after the expiration date of 02/23/2025. 3. An exit interview, with the Technical Consultant and the Testing Personnel, on August 14, 2025, at 2:00pm, confirmed that laboratory failed to perform the required biannual speed calibration, 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 2023 - 2025 Maintenance Records, 2023 - 2025 Temperature Records, 2023 - 2025 Personnel Records, 2023 - 2025 Proficiency Testing Records, 2023 - 2025 Quality Control Records, and 2023 - 2025 Quality Assurance Records confirmed that the Laboratory Director failed to perform the required oversight for all laboratory operations. Refererece: D5401, D5413, D5417, D5429, D6020, and D6046.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (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 2023 - 2025 Maintenance Records, 2023 - 2025 Temperature Records, 2023 - 2025 Personnel Records, 2023 - 2025 Proficiency Testing Records, 2023 - 2025 Quality Control Records, and 2023 - 2025 Quality Assurance Records confirmed that the Laboratory Director failed to perform the required quality assurance assessment of laboratory operations to assure quality laboratory service. THE FINDINGS INCLUDE: 1. A review of the aforementioned records confirmed that quality assessment was conducted by the Technical Consultant and the Testing Personnel with no review by the Laboratory Director to identify failures. 2. An exit interview, with the Technical Consultant and the Testing Personnel, on August 14, 2025, at 2:00pm, confirmed that the Laboratory Director failed to perform the required quality assurance assessment of laboratory operations to assure quality laboratory services.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (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. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: A review of 2023 - 2025 Personnel Records confirmed that the Technical Consultant failed to perform personnel competency on two out of two testing personnel. THE FINDINGS INCLUDE: 1. A review of 2023 - 2025 Personnel Records confirmed that one out of two competencies were conducted by unqualified Testing Personnel. Testing Personnel 1 (See CMS- Form 209 Laboratory Personnel Report) performed the require six (6) month competency on Testing Personnel 2 (See CMS- Form 209 Laboratory Personnel Report). 2. A review of 2023 - 2025 Personnel Records revealed that a Letter of Delegation of Duties, from the Laboratory Director, for Testing Personnel 1 (See CMS- Form 209 Laboratory Personnel Report), was not available at

	the time of inspection. 3. An exit interview, with the Technical Consultant and the Testing Personnel, on August 14, 2025, at 2:00pm, confirmed that the Technical Consultant failed to perform personnel competencies on two out of two laboratory testing personnel.