Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0910844	08/13/2025
Name of Provider or Supplier	**Street Address, City, State**	
Evans Medical Group	1205 Town Park Lane, 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 13, 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:
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: A review of the current Procedure Manual (SOP) confirmed that the SOP failed to contain step by step procedures for all testing procedures in the laboratory. THE

	FINDINGS INCLUDE: 1. A review of the SOP revealed that ALL tests, assays, and examinations performed by the laboratory were not available at the time of survey. 2. A review of of the SOP revealed the recording maintenance log sheets and temperatures were within the SOP manual. Written step-by-step procedures were not avaible at the time of inspection. 3. A review of the SOP revealed there were no Down Time, Maintenance, Temperature Monitoring, Specimen Handling & Storage or Quality Control Procedures. 4. A review of The Safety Procedure confirmed that details of the fire extinguishers location, fire extinguisher operations, evacuation plans, were not available at the time of inspection. 5. An exit interview, with the Technical Consultant and the Testing Personnel, on August 13, 2025, at 2:00pm confirmed that the SOP manual did not to contain step by step procedures for all testing procedures 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 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 Reagent Storage Freezer confirmed a temperature range of -20C - 0C, per the Temperature Logsheet. 2. A review of the BIO-RAD LiquiChek Immunoassay Plus Controls confirmed a storage requirement of -70C - -20C. The reagents were stored in the Reagent Storage Freezer with a temperature range of -20C - 0C. 3. A review of the closet, used for storage of supplies , revealed that the temperature of the closet storage area was not monitored. The following reagent and supplies were stored in this unmonitored closet: a. BD VACUTAINERS with temperature storage requirements of 4C - 25C; b. TOSOH G8 VARIANT ELUTION BUFFER HSi with temperature storage requirements of 4C - 30C; and c. TOSOH HSi HEMOLYSIS & WASH SOLUTION-(L) with temperature storage requirements of 4C - 30C. 5. An exit interview, with the Technical Consultant and the Testing Personnel, on August 13, 2025, at 2:00pm confirmed that reagents were not stored as required by the manufacturer.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: A tour of the laboratory confirmed that Laboratory Personnel were using expired

	reagents at he time of survey. THE FINDINGS INCLUDE: 1. A review of the contents of the reagent storage refrigerator revealed that 2 bottles of the Beckman Coulter Cleaning Solution, in use, expired O3/01/2025 and 3 bottles expired on 03/15 /2025. 2. A review of the room temp reagents in the laboratory revealed that 3 bottles of ACCESS Wash Buffer II, in use, expired on 02/28/2025. 3. A review of the cabinet storage space, in the laboratory, revealed that Becton Dickson Yellow Top Microtainer Collection Tubes, in use, expired on 07/31/2022. 4. An exit interview, with the Technical Consultant and the Testing Personnel, on August 13, 2025, at 2: 00pm confirmed that the expired reagents were in use for clinical laborstory testing at the time of survey.
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 tour of laboratory facility and review of the current Procedure Manual, 2023 - 2025 Personnel Records, and 2023 - 2025 Maintenance Records confirmed that the Laboratory Director (LD) failed to provide proper oversight of the overall operations and administration of the Laboratory. Refer to D5403, D5413, D5417, D6011 and D6030.
D6011	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) (e)(2) provide a safe environment in which employees are protected from physical, chemical, and biological hazards; This STANDARD is not met as evidenced by: A tour of the facility and a review of the Procedure Manual (SOP) confirmed that the Laboratory Director failed to provide a safe work environment for laboratory personnel. THE FINDINGS INCLUDE: 1. A tour of the facility confirmed that all six (6) fire extinguishers, on site, were last inspected 12/21/2022. 2. A review of the current SOP revealed that the Safety Procedure did not contain details on the location of the fire extinguishers, did not contain instructions on the proper use of the fire extinguishers, and did not contain an evacuation procedure in the event of a fire. 3. An interview with the Technical Consultant and Lab Personnel revealed that the staff had not been trained on the safety and evacuation procedures of the laboratory 4. An exit interview with the Technical Consultant and the Testing Personnel, on August 13, 2025, at 2:00pm confirmed that the Laboratory Director failed to provide a safe work environment for laboratory personnel.

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 2023 - 2025 Personnel Records confirmed that the Laboratory Director (LD) failed to perform a competency assessment for the Technical Consultant (TC). THE FINDINGS INCLUDE: 1. A review of the 2023 - 2025 Personnel Records revealed that the 2024 competency performed on the TC was signed by the TC on 10 /15/ 2024 and signed by the LD on 02/27/2025. 2. A review 2024 competency documentation revealed that the TC performed her own competency which the LD later signed. 3. An exit interview, with the Technical Consultant and the Testing Personnel, on August 13, 2025, at 2:00pm, confirmed that the LD failed to perform the competency on the TC.