Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0948779	06/13/2025
Name of Provider or Supplier	**Street Address, City, State**	
Byron Family Health Care	200 Hwy 49 South, Byron, 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 June 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 Laboratory Procedure Manual (SOP) confirmed that the Procedure Manual failed to contain procedures for all laboratory operations. THE

	FINDINGS INCLUDE: 1. A review of the current Laboratory Procedure Manual confirmed that a Downtime Retrieval and Retention Procedure and a Quality Assurance Procedure and a Maintenance Procedure was not available at the time of inspection. 2. An exit interview with the Laboratory Director, Technical Consultant, and Testing Personnel on June 13, 2025 at 12:00pm in the Conference Room confirmed that the Procedure Manual failed to contain procedures for all laboratory operations.
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 revealed that expired reagent was in use for patient testing and reporting. THE FINDINGS INCLUDE: 1. A tour of the Laboratory found multiple expired reagents in use for testing. The expired reagents noted as follows: a. BBL CULTURE SWAB PLUS- expiration date of 05/31/2025. b. CHOLESTECH LDX CAPILLARY TESTING TUBES- expiration date of 06/09. c. HOLOGIC APTIMA COLLECTION DEVICE- expiration date of 12/31/2022. d. MCKESSON POVIDONE-IODINE USP SWABSTICKS- expiration date of 08/14/2019. e. MEDLINE HCG TEST CASSETTES - expiration date of 03/31/2025. f. MEDLINE STREP A TEST STRIPS- expiration date of 02/27/2025. g. OSOM INFLUENZA A/ B TEST KIT- expiration date of 05/31/2025. 2. An exit interview with the Laboratory Director, Technical Consultant, and Testing Personnel on June 13, 2025 at 12:00pm, in the Conference Room confirmed that expired reagent was in use for patient testing and reporting.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: A review of random in-house testing and sendout testing test reports confirmed that the Patient Test Results Reports failed to include all required information per regulations. THE FINDINGS INCLUDE: 1. A review of a random patient test report confirmed that the name and address of the laboratory location, where the test was performed, was not documented on the test reports. 2. An exit interview with the Laboratory Director, Technical Consultant, and Testing Personnel on June 13, 2025 at 12:00pm in the Conference Room confirmed that the patient test results reports failed to include all required test report information.

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 Laboratory confirmed that the Laboratory Director failed to provide a safe environment in which employees are protected from physical, chemical, and biological hazards. THE FINDINGS INCLUDE: 1. A tour of the Laboratory confirmed that an eyewash station was not installed in the clinical testing location of the laboratory. 2. An exit interview with the Laboratory Director, Technical Consultant, and Testing Personnel on June 13, 2025 at 12:00pm in the Conference Room confirmed that the Laboratory Director failed to provide all the neccessary protections, in the laboratory, from physical, chemical, and biological hazards.
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 monitor the competency of all laboratory personnel. THE FINDINGS INCLUDE: 1. A review of 2023 - 2025 Personnel Records confirmed that the 2023 - 2024 competencies for TP1; 2023 competencies for TP2; 2023 competencies for TP3, and 2023 - 2024 competencies for TC1 were not completed. (see CMS-209 Personnel form). 2. An exit interview with the Laboratory Director, Technical Consultant, and Testing Personnel on June 13, 2025 at 12:00pm in the Conference Room confirmed that the LD failed to monitor the competency of all laboratory personnel.