Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0992000	12/16/2025
Name of Provider or Supplier	**Street Address, City, State**	
Dublin Hematology & Oncology Care Pc	207 Fairview Park Drive - Dublin, Dublin, 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 December 16, 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:
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: HO DA review of the 2023 - 2025 Laboratory Records which included the Personnel Records, Proficiency Testing Records Quality Control Records, Temperature Records, current Laboratory Procedure Manual, and laboratory tour confirmed that the laboratory failed to establish and maintain a quality assurance system to monitor the overall quality of the laboratory systems and provided corrective action measures. THE FINDINGS INCLUDE: 1. A review of 2023 - 2025 laboratory records revealed that Quality Assurance Review documentation was not completed. 2. A review of the 2023 - 2025 Laboratory records confirmed that Maintenance Performance Records were not performed as required by CLIA Regulation 493.1254(b)(1)(ii). 3. A review of the 2023 - 2025 Cell-Dyn Emerald Quality Control Records revealed erratic trending of the Erythrocyte parameter which was unidentified and had no corrective actions. 4. A review of the 2023 - 2025 Temperature Records revealed that the established temperature ranges were not documented on the Temperature Logs. 5. An exit interview, with Testing Personnel 1 (see CMS-209 personnel form) on December

	16, 2025, at 1:00pm, confirmed that the laboratory failed to establish and maintain a quality assurance system to monitor the overall quality of the laboratory systems.
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 Laboratory Procedure Manual confirmed that the laboratory failed to establish procedure manuals as required by CLIA or adhere to existing procedures. THE FINDINGS INCLUDE: 1. A review of the Laboratory Procedure Manual revealed that a Down Time Procedure, Maintenance Procedure, Personnel Procedure, Quality Assurance Procedure, Quality Control Procedure, Safety Procedure, and a Safety Procedures were not available. 2. A review of existing procedure manuals confirmed that normal ranges and critical values were not documented. 3. A review of the Procedure Manual confirmed that a step-by-step procedure for the Complete Blood Count testing which contained all required elements as set forth in CLIA Regulation 493.1251(b)(1), (b)(3), (b)(5)-(b)(14), was not available. 4. A review of the Laboratory Procedure Manual revealed that testing personnel failed to adhere to the PHLEBOTOMY VENIPUNCTURE SOP p3, #14 which requires that testing specimen collectors "Label all tubes with the patient's ID number, last and first name, date, time of draw, tests ordered, and nurse's/ phlebotomist's initials." Specimen tubes for testing were located in the laboratory testing area with only partial patient names. 5. An exit interview, with Testing Personnel 1 (see CMS Personnel Form-209) on December 16, 2025, at 1:00pm confirmed that the laboratory failed to establish procedure manuals as required by CLIA or adhere to existing procedures.
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 the 2023 - 2025 Laboratory Records which included a review of Personnel Records, Proficiency Testing Records Quality Control Records, Temperature Records, current Laboratory Procedure Manual, and laboratory tour confirmed that the Laboratory Director failed to provide overall oversight of the laboratory operations to assure quality clinical laboratory testing results. Reference: D5200, D5403