Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2060348	02/27/2025
Name of Provider or Supplier	**Street Address, City, State**	
Cancer Center Of Middle Georgia, Llc	2400 Bellevue Road Ste 26, 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 recertification survey was performed on February 27, 2025. The facility was found to be NOT in compliance with the CLIA conditions and standards for specialties /subspecialties for 42 CFR. CONDITION LEVEL: D-6000 Moderate Complexity Laboratory Director 493.1403 NOTE: The CMS-2567 (Statement of Deficiencies) is an official , legal document,. All information must remain unchanged except for entering the Plan Of Correction (POC), correction dates, and the signature space. Any discrepancy n the original deficiency citation(s) will be reported the the Georgia Regional Office (RO) for referral the Office of the Inspector General (OIG) for possible fraud if the information is inadvertently changed by the provide/supplier, the State Survey Agency (SA) should be notified immediately.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) (b)The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of the 2023 and 2024 American Proficiency Institute (API) Proficiency Testing (PT) documents, and staff interview, the laboratory failed to perform testing on the PT samples provided in the same manner as it tests patient specimens. Findings: 1. Review of the 2nd event for the Specialty of Hematology, 2023 API PT documents , the Attestation Statement provided was not signed by the Laboratory Director (LD) confirming that the PT samples were tested in the same

	manner as patient samples. Three different TP tested the samples on the same day, outside of the nornal testing procedures. Review of the 3rd event for the Specialty of Hematology, 2023 API PT documents, the Attestation Statement provided (received by email on 3/13/2025) shows that the PT samples were tested by two testing personnel (TP), on the same day, outside of the normal testing procedures. Review of the 1rst event for Specialty Hematology, 2024 API documents, the Attestation Statement provided was not available on the day of the survey and was received on 3 /13/2025 by email. This document shows that the PT samples were tested by two TP on the same day. Review of the 3rd event for the Specialty Hematology, 2024 API documents, the attestation Statement provided was not available on the day of the survey and was received on 3/13/2025 by email. This document shows that PT samples were testing by two TP on the same day, outside of the normal testing procedures. 2. Interview with TP-1 and TP-2 on 02/29/2025 at approximately 12 pm in the laboratory, confirmed that the attestation documents were not available at the time of the survey.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the Quality Control (QC) documents for 2025, and staff interview the laboratory failed to provide corrective action for the Normal QC for Specialty Hematology, Subspecialties, Red Blood Cell (RBC) and Hemoglobin (HGB). FINDINGS: 1. Review of the QC document for 2025, Specialty Hematology, Sub-specialty RBC and HGB, for 2/11/2025 - 2/14/2025, the Normal QC Level was out of range. There were no corrective action documented for the Normal QC being out consecutively for four days. 2. Interview with Testing Personnel (TP) TP-1 and TP-2 in the laboratory on 2/27/2025 at approximately 12:05 pm confirmed the statement above.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the Quality Control (QC) Documents from 2023, 2024, and 2025, and the Proficiency Testing (PT) documents from 2023 - 2024, the Laboratory Director failed to provide overall management and direction in the Laboratory. This is a CONDITION Level Citation 493.1403 REFERENCE: D-Tag 6003 Laboratory Director Qualifications 493.1421 D-Tag 6024 Laboratory Director Responsibilities 493.1407e7 D-Tag 6046 Technical Consultant Responsibilities 493.1413b8

D6003	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1405 AND 493.1406 The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; and (b)(2)(ii)(B) Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in 493. 1407; or (b)(3)(i)(A) Hold an earned doctoral degree in a chemical, biological, clinical or medical laboratory science or medical technology from an accredited institution; or (b)(3)(i)(B) Hold an earned doctoral degree; and (b)(3)(i)(B)(1) Have at least 16 semester hours of doctoral level coursework in biology, chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS); or (b)(3)(i)(B)(2) An approved thesis or research project in biology/chemistry /MT/CLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and (b)(3)(ii) Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in 493.1407; and (b)(3)(ii)(A) Be certified and continue to be certified by a board approved by HHS; and (b)(3)(ii)(B) Have had at least 1 year of experience directing or supervising nonwaived laboratory testing; or (b)(4)(i)(A) Have earned a master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B)(1) Meet bachelor's degree equivalency; and (b)(4)(i)(B)(2) Have at least 16 semester hours of additional graduate level coursework in biology, chemistry, medical technology, clinical or medical laboratory science; or (b)(4)(i)(C)(1) Meet bachelor's degree equivalency; and (b)(4)(i)(C)(2) Have at least 16 semester hours in a combination of graduate level coursework in biology, chemistry, medical technology, clinical or medical laboratory science coursework and an approved thesis or research project related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and (b)(4) (ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing; and (b)(4)(iii) Have at least 1 year of supervisory laboratory experience in nonwaived testing; and (b)(4)(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1407; or (b)(5)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(5)(i) (B) At least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either- (b)(5)(i)(B)(1) 48 semester hours of medical laboratory science or medical laboratory technology courses; or (b)(5)(i)(B)(2) 48 semester hours of science courses that include- (b)(5)(i)(B)(2)(i) 12 semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry; and (b) (5)(i)(B)(2)(ii) 12 semester hours of biology, which must include general biology and molecular biology, cell biology or genetics; and (b)(5)(i)(B)(2)(iii) 24 semester hours

	of chemistry, biology, or medical laboratory science or medical laboratory technology in any combination; and (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing; and (b)(5)(iii) Have at least 2 years of supervisory laboratory experience in nonwaived testing; and (b)(5)(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1407. (b)(6) Notwithstanding any other provision of this section, an individual is considered qualified as a laboratory director of moderate complexity testing under this section if they were qualified and serving as a laboratory director of moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. This STANDARD is not met as evidenced by: Based on review of the listed Laboratory Director's curriculum vitae (CV), Educational Documents, Fellowships, certifications, and staff interview, the current acting Laboratory Director (LD) does not meet the qualifications to be qualified to be the Laboratory Director, under 493.1405(a)(b). Findings: 1. There was no documentation presented to show that the LD is certified in Anatomic or Clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology. 2. There was no documentation presented to show the LD, has had laboratory training, or had served as the LD of a moderately complexity laboratory before 12/28/2024. 3. Phone interview with the Office Manager on 03/19 /2025, at approximately 10:30 am confirmed the Laboratory does not have laboratory experience, and does not have the 20 hours Continuing Education units.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratorys established performance specifications are identified, and that patient test results are reported only when the system is functioning properly; This STANDARD is not met as evidenced by: Based on review of the Quality Control (QC) documents for 2025, and staff interview, the Laboratory Director (LD) failed to make sure corrective action for the Normal QC for Specialty Hematology, Subspecialties- Red Blood Cell (RBC) and Hemoglobin (HGB) was provided. FINDINGS: 1. Review of the QC document for 2025, Specialty Hematology, Sub-specialty RBC and HGB, for 2/11/2025 to 2/14/2025, the Normal QC Level was out of range. There was no corrective action provided for the Normal QC being out of range for four consecutive days. 2. Interview with Testing Personnel (TP) TP-1 and TP-2 in the laboratory on 2/27/2025 at approximately 12:05 pm confirmed the aforementioned statement.
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: Based on review of the educational, training, and competency documents for the 2 listed Testing Personnel (TP) on the Centers for Medicare and Medicaid Services (CMS) form 209, the Laboratory Director listed as the Technical Consultant on the CMS form Laboratory Personnel Report (form 209), and staff interview failed to evaluate the competency of all testing personnel and assure that the staff maintained competency to perform test procedures and report test results promptly, accurately and proficiently. The following six procedures are the minimum regulatory requirements for assessment of competency for all personnel performing testing: Direct observation of routine patient test performance, Monitoring test results, Review of intermediate test results, Direct observation, Assessment of test performance, Assessment of problem solving. FINDINGS: 1. For testing personnel TP-1, there is an initial training document dated 10-16-24, labeled 2 weeks, the method of determination of competency was not described on the document. Subsequent document for the same TP-1, dated 2/19/2025 labeled 6 week, the method of competency determination was not described on the document. The educational documented was a copy of a Diploma for Medical Assisting from a Technical College. No High School diploma was available on the date of survey. 2. For testing personal TP-2, there is a initial training documented dated 01/15/2025, labeled 2 weeks, the method of determination of competency was not described on the document. Subsequent document for the dame TP-2 dated 11/13/2024, labeled 6 weeks, the method of competency determination was not described on the document. There were no educational documents for TP-2. 3. Interview with the both TP, in the laboratory on 02/27/2025, at approximately 12 pm, confirmed the statements above.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report (CMS form 209) and staff interview, the laboratory failed to provide educational documents for the 2 Testing Personnel (TP) listed on the 209 form. Findings: 1. Review of TP-1 educational documents confirmed that a diploma from a Technical College was awarded for Medical Assisting. This is not equivalent to a High School Diploma. A review of TP-2 educational documents, or

	the lack there of, confirmed there were no documents available for review. 2. Interview with TP-1 and TP-2, on 02/27/2025 in the laboratory at approximately 12: 15 pm, confirmed the statements above.