Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0187805	01/25/2024
Name of Provider or Supplier	**Street Address, City, State**	
Cancer Care Associates Of York	25 Monument Road Suite 294, York, PA	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the American Association of Bioanalysts- Medical Laboratory Evaluation AAB-MLE) proficiency testing (PT) records, lack of documentation, and interview with the technical consultant (TC), the laboratory director (LD)/designee and testing personnel (TP) failed to sign 6 of 6 AAB-MLE PT attestation statements for chemistry and hematology testing performed in 2023. 1. The AAB-MLE PT instructions state, "be sure to keep the attestation statements printed from your online reporting form. We do not require this for grading. The attestation statements must be signed for each analyte by the analyst performing the procedure and kept in your files for inspection purposes. In addition to the analysts' signatures, the director or the director's designee must sign only once for each reporting form." 2. On the day of the survey, 01/25/2024 at 11:00 am, the laboratory failed to provide attestation statements signed by the LD/designee and TP for the following 6 of 6 AAB-MLE events in 2023 for hematology and chemistry testing: - Chemistry M1 - Chemistry M2 - Chemistry M3 - Nonchemistry M1 - Nonchemistry M2 - Nonchemistry M3. 3. The TC confirmed the findings above on 01/25/2024 at 01:30 pm.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not

	provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, operator manuals, and interview with the technical consultant (TC), the laboratory failed to have a complete written procedure manual for chemistry testing performed on the Ortho Clinical Diagnostics Vitros that met the requirements of 493.1251 from 5/12/2022 to the date of the survey. Findings include: 1. On the day of the survey, 01/25/2024 at 11:30 am, review of the procedure manuals for chemistry testing revealed the operators manual was used when performing chemistry testing on the Ortho Clinical Diagnostics Vitros from 05 /12/2022 to 01/25/2024. 2. Review of the operators manual revealed that the test system instructions used failed to include the following requirements of 493.1251: - 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 - Step by step performance of the procedure including test calculations and interpretation of results - Preparation of slides, solution, calibrators, controls, reagents, stains, and other material used in testing. - Control procedures - Calibration and calibration verification procedures. - The reportable range for test results for the test system as established or verified in 493.1253. - Corrective action to take when calibrations or control results fail to meet the laboratory criteria for acceptability - Limitations in the test methodology, including interfering substances. - Reference intervals (normal values). - 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. - Description of the course of action to take if a test system becomes inoperable. 3. The TC confirmed the findings above on 1 /25/2024 at 01:30 pm.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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: Based on review of the laboratory's temperature records, and interview with the technical consultant (TC), the laboratory failed to monitor and document room, refrigerator, and freezer temperatures to ensure operating conditions were met for the proper storage of chemistry and hematology reagents from 5/12/2022 to day of survey. Findings Include: 1. On the day of the survey, 1/25/2024 at 12:50 pm, review of the laboratory's temperature control logs revealed that the laboratory failed to monitor and document temperatures for the room, 1 of 1 refrigerator and 1 of 1 freezer used for the storage of chemistry (Ortho Vitros and Tosoh) and hematology (Sysmex XS-1000i) reagents on weekends and holidays when personnel were not on site in the

	laboratory from 05/12/2022 to 01/25/2024. 2. The hours of laboratory testing are Monday-Friday 07:45 am to 04:30 pm (CMS 116). 3. The TC confirmed the findings above on 1/25/2024 at 01:30 pm.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of documentation, and interview with the technical consultant (TC), the laboratory failed to perform and document the maintenance/ function checks for 3 of 3 thermometers used to monitor refrigerator, freezer, and room temperatures used for storage of chemistry and hematology reagents from 05/12/2022 to the day of survey. Findings Include: 1. On the day of survey, 01/25 /2024 at 12:50 pm, the laboratory could not provide maintenance/function check records for the following 3 of 3 thermometers used to monitor refrigerator, freezer, and room temperatures used for storage of chemistry and hematology reagents from 05 /12/2022 to 01/25/2024: - S/N 210714102: exp: 08/22/2023 - S/N 210639919: exp: 07 /26/2023 - S/N 160121337: exp: 01/14/2018 2. The TC confirmed the findings above on 01/25/2024 at 01:30 pm.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on record review and interview with the technical consultant (TC), the laboratory director (LD) failed to ensure that verification procedures used were adequate to determine the accuracy, precision, and other pertinent performance characteristics when chemistry tests were performed on the Tosoh analyzer from 05/12 /2022 to the date of the survey. 1. The laboratory's Role of Laboratory Director and Delegates in Cancer Care Associates of York Laboratory procedure states,"it is the sole, non-delegable responsibility of the CCAY Laboratory Director to maintain oversight to ensure that: testing systems in the laboratory provide quality services in all aspects of test performance." 2. On the date of the survey, 01/25/2024 at 12:35 pm, review of the laboratory's calibration verification records revealed the laboratory failed to provide documentation of the review by appropriate personnel to ensure the accuracy of the test system met the laboratory's established acceptable limits for calibration verifications performed for the following analytes in 2022 and 2023: - Calibration verification performed April 2023 for Ferritin and Prostate Specific Antigen (PSA) on the Tosoh chemistry analyzer. - PSA calibration verification

	performed October 2022 was not reviewed until January 2023. 2. The TC confirmed the findings above on 01/25/2024 at 01:30 pm.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the American Association of Bioanalysts- Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory director (LD) failed to ensure that all PT reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and identify any problems that require corrective action for chemistry and hematology testing performed in 2022 and 2023. Findings include: 1. On the day of survey, 1/25/2024 at 11:00 am, review of the laboratory's AAB-MLE PT records revealed the LD/designee failed to review and assess the following 1 of 6 AAB-MLE PT reports reviewed for 2022 and 2023: - 2023 AAB-MLE Nonchemistry Event #3 2. The laboratory failed to provide documentation of the corrective action taken when the laboratory received an unacceptable score for the following PT analytes/events: - AAB-MLE 2022 Chemistry: Nitrite (urinalysis): 0%, Aspartate aminotransferase (AST): 80% 3. The TC confirmed the findings above on 1/25/2024 at 01:30 pm.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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. (e) The laboratory director must-- (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: A. Based on review of the Sysmex XS-1000i calibration records and interview with the technical consultant (TC), the laboratory failed to perform calibrations every six months as recommended by the manufacturer for 2 of 2 Sysmex XS-1000i hematology analyzers from 5/12/2022 to the day of survey. Findings include: 1. The laboratory's Sysmex XS-1000i procedures states, "The laboratory must verify calibration every six months. " 2. On the date of the survey, 01/25/2024 at 12:25 pm, the laboratory failed to provide documentation for the calibrations performed every six months for 2 of 2 Sysmex XS-1000i hematology analyzers (SN#: 74500/74501) in 2022 and 2023. 3. The TC confirmed the findings above on 1/25/2024 at 01:30 pm. B. Based on lack of documentation and interview with the technical consultant (TC), the laboratory failed to evaluate twice a year the relationship between test results for 2 of

	2 Sysmex XS-1000i hematology analyzers from 5/12/2022 to the day of the survey. Findings include: 1. On the day of the survey, 1/25/2024 at 12:00 pm, the laboratory failed to provide documentation of the biannual comparison of test results between 2 of 2 Sysmex XS-1000i hematology analyzers for the complete blood counts (CBC) performed in 2022 and 2023. 2. The laboratory performed 209,488 hematology tests in 2023 (annual volume listed on CMS-116). 3. The TC confirmed the findings above on 1/25/2024 at 01:30 pm.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (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. This STANDARD is not met as evidenced by: Based on review of the laboratory's competency assessment records and interview with the technical consultant (TC), the TC failed to assess the competency of 1 of 24 testing personnel (TP) that performed chemistry, hematology, and endocrinology testing from 5/12/2022 to the date of the survey. Findings include: 1. On the day of survey, 01/25/2024 at 9:30 am, review of the laboratory's competency assessment records revealed the TC failed to assess the competency of 1 of 24 TP (CMS 209 TP#3) that performed chemistry (Vitros Ortho Clinical Diagnostics analyzer), endocrinology (TOSOH analyzer), and hematology (Sysmex XS-100) testing from 05 /12/2022 to 01/25/2024. 2. The TC confirmed the findings on 1/25/2024 at 01:30 pm. *Repeat Deficiency
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the technical consultant (TC), the laboratory failed to have the required records accessible during the laboratory survey performed on 01/25/2024. Findings Include: 1. On the day of the

	survey, 01/25/2024 at 01:00 pm, the laboratory could not provide the following records upon request: - Quality control records for the Sysmex XS-1000i, Ortho Vitros, and Tosoh - Monthly review of quality control peer group reports 2. The TC confirmed the finding above on 01/25/2024 at 01:00 pm.