Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0682375	11/21/2024
Name of Provider or Supplier	**Street Address, City, State**	
Cancer Care Associates, P C	3577 W Thirteen Mile Road, Suite 404, Royal Oak, MI	

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
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on observations, record review, and interviews, the laboratory failed to follow testing personnel competency assessment policies and procedures (refer to D5209), failed to ensure controls and supplies were not used beyond expiration dates (refer to 5417), failed to establish maintenance activities for laboratory thermometers (refer to D5433) and failed to document chemistry quality control (refer to D5445A).
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on record review and interview, the laboratory failed to follow testing personnel competency assessment policies and procedures (refer to D5417) and failed to document hematology quality control (refer to D5445B).
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235

	As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager (OM), the laboratory failed to follow testing personnel competency assessment policies and procedures for 1 (TP2) of 2 testing personnel. Findings include: 1. A record review of the laboratory's personnel records revealed that competency assessments were not conducted for Testing Personnel #2 (TP2) upon hire (February 14, 2024) nor in August of 2024 when TP2 commenced patient testing. 2. Review of laboratory policy titled "Personnel Experience, Qualifications and Training" revealed "...5. A personnel file is kept on each laboratory employee. This will include: a. Initial and 6-month training and competency documentation...". 3. An interview with the OM on 11/21 /2024 at 3:55 pm confirmed that competency assessment documentation for TP2 was not present at time of survey.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: . Based on observation, record review and interview with Testing Personnel #1 (TP1), the laboratory failed to document the specimen collection time for two of four patient samples observed in the laboratory. Findings include: 1. On 11/21/24 at 1:22 pm, the surveyor observed two patient samples, a gold top blood collection tube and a green top blood collection tube, in the specimen processing area that were not labeled with the time the specimens were collected. 2. Review of the laboratory's policy titled "Specimen Collection and Handling" revealed "Patient Identification and Specimen Labeling ...Each specimen must be correctly identified and labeled with the following information: Patient's full name DOB Time and date of collection ..." 3.An interview on with TP1 at 11/21/2024 at 1:25 pm confirmed that collection times were not documented on the two patient samples observed.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: . Based on observation and interview with Testing Personnel #1 (TP1), the laboratory failed to ensure controls and supplies were not used beyond expiration dates for four items observed. Findings include: 1. During a tour of the laboratory on 11/21/2024 at 9:45 am the surveyor observed the following: a. Two bottles Bio-Rad Liquid Assay Controls with the expiration date of 11/20/2024. b. One bottle of Millipore Cleansing Tablets with the expiration date of 06/22/2022. c. One Millipore Water Filter with the

	expiration date of 9/11/2024 installed on the Merck Water Filtration System for the laboratory's Siemens Dimension Expand Plus Chemistry Analyzer. 2. An interview was conducted with TP1 on 11/21/2024 at 10:00 am confirmed controls and supplies were expired.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with Testing Personnel #1 (TP1), the laboratory failed to establish maintenance activities for laboratory thermometers for 5 (July 2024-November 2024) of 5 months. Findings include: 1. On 11/21/2024 at 3:00 pm during tour of the back storage room the surveyor observed the following: a. A mini-refrigerator containing quality controls in the freezer compartment. The freezer was noted to have an accumulation of ice. The freezer thermometer displayed a temperature reading of -31 degrees Celsius. b. A stand alone refrigerator containing reagents in the refrigerated section. The thermometer of the refrigerated section displayed a temperature reading of 8 degrees Celsius. Further inspection of the thermometer revealed a calibration expiration date of 06/22/2024. 2. Record review of the laboratory's "Temperature Documentation For Minimax Thermometers" logs revealed thermometer calibration was not monitored. 3. An interview with TP1 on 11/21/2024 at 3:05 pm confirmed the thermometer calibration had expired.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . A. Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to document chemistry quality control for 9 (#1-9) of 10 patient testing dates requested for review. Findings include: 1. Record review for patients receiving chemistry testing revealed a lack of quality control documentation for the following 9 patient testing dates: a. Patient #1 had comprehensive metabolic panel (CMP), ferritin, and iron panel performed on 11/04/2024. b. Patient #2 had hepatic function panel (HFP) and basic metabolic panel (BMP) performed on 08/01/2024. c.

	Patient #3 had CMP, magnesium, ferritin, and iron panel performed on 06/27/2024. d. Patient #4 had CMP performed on 06/05/2024. e. Patient #5 had CMP and magnesium performed on 05/13/2024. f. Patient #6 had CMP performed on 02/14/2024. g. Patient #7 had CMP performed on 11/15/2023. h. Patient #8 had CMP performed on 06/06 /2023. i. Patient #9 had CMP performed on 03/08/2023. 2. An interview with TP1 on 11/21/2024 at 3:00 pm confirmed quality control documentation was not retrievable. B. Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to document hematology quality control for 10 (#1-10) of 10 patient testing dates requested for review. Findings include: 1. Record review for patients receiving hematology testing revealed a lack of quality control documentation for the following 10 patient testing dates: a. Patient #1 had complete blood count (CBC) with differential performed on 11/04/2024. b. Patient #2 CBC with differential performed on 08/01/2024. c. Patient #3 CBC with differential performed on 06/27/2024. d. Patient #4 CBC with differential performed on 06/05/2024. e. Patient #5 CBC with differential performed on 05/13/2024. f. Patient #6 CBC with differential performed on 02/14/2024. g. Patient #7 CBC with differential performed on 11/15/2023. h. Patient #8 CBC with differential performed on 06/06/2023. i. Patient #9 CBC with differential performed on 03/08/2023. j. Patient #10 CBC with differential performed on 1/03/2023. 2. An interview with TP1 on 11/21/2024 at 3:00 pm confirmed quality control documentation was not retrievable.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager, the laboratory failed to document postanalytic systems quality assessment activities for 5 (June 2024 - October 2024) of 21 months reviewed. Findings include: 1. Review of the laboratory's quality assessment monthly review records revealed that documentation for June 2024, July 2024, August 2024, and October 2024 was not present. 2. An interview with the Office Manager on 11/21/2024 at 3:50 pm confirmed documentation of postanalytic systems quality assessment activities for June 2024 through October 2024 was missing.
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 record review, observations, and interviews, the Laboratory Director failed to ensure ensure controls were not used beyond expiration dates (refer to D6020A), failed to ensure maintenance activities were established for laboratory thermometers

	(refer to D6020B), failed to ensure documentation of chemistry quality control (refer to D6020C), failed to ensure documentation of hematology quality control (refer to 6020D), failed to ensure documentation of quality assessment programs were maintained (refer to D6021), and failed to ensure competency assessment policies and procedures were followed (refer to D6029).
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: A. Based on observation, record review and interview the laboratory director failed to ensure controls were not used beyond expiration dates (refer to D5417). B. Based on observation, record review, and interview the laboratory director failed to ensure maintenance activities were established for laboratory thermometers (refer to D5433). C. Based on record review, and interview the laboratory director failed to ensure documentation of chemistry quality control (refer to D5445A). D. Based on record review and interview, the laboratory director failed to ensure documentation of hematology quality control (refer to D5445B).
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: . Based on record review and interview the laboratory director failed to ensure documentation of postanalytic systems quality assessment activities (refer to D5893).
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

	This STANDARD is not met as evidenced by: Based on record review and interview the laboratory director failed to ensure competency assessment policy was followed (refer to D5209).