Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0187805	11/14/2025
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
D0000	An initial survey was conducted by the Pennsylvania State Agency at Cancer Care Associates of York on 11/14/2025. The laboratory was found out of compliance with the following condition: 493.1250 Condition: Analytic Systems.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Technical Consultant (TC), the laboratory failed to verify twice annually the accuracy of 1 of 1 chemistry test (Vitamin D 25-OH) performed from 4/28/2025 to 11/14/2025. Findings include: 1. On the day of survey, 11/14/2025 at 11:12 am, the laboratory could not provide documentation for the verification of accuracy performed at least twice annually for 1 of 1 chemistry test (Vitamin D 25-OH) performed from 4/28/2025 to 11/14/2025. 2. The TC revealed during interview, 11/14/2025, the laboratory performed 147 Vitamin D 25-OH tests from 4/28/2025 to 9/30/2025. 3. The TC (CMS 209 personnel #2, dated 11/06/2025) confirmed the findings above on 11/14/2025 at 1:30 pm.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

	This CONDITION 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 meet applicable analytic systems requirements in 493.1251, 493.1252 and 493.1254 for 21 of 21 months from 1/25 /2024 to date of survey. Refer to D5407, D5413 and D5429.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's Chemistry procedure manuals, lack of documentation, and interview with the Technical Consultant (TC), the Laboratory Director (LD) failed to ensure an approved policy for the Vitros 3400 chemistry analyzer and AIA Tosoh chemistry analyzer were available to all personnel from 1/25 /2024 to 11/14/2025. Findings include: 1. On the date of survey, 11/14/2025 at 12:04 pm, the LD failed to provide an approved policy for the Vitros 3400 chemistry analyzer and AIA Tosoh chemistry analyzer used for testing from 1/25/2024 to 11/14 /2025. 2. The TC (CMS 209 personnel #2, dated 11/06/2025) confirmed the findings above on 11/14/2025 at 1:30 pm.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 observation of the laboratory, review of laboratory temperature records and interview with the Technical Consultant (TC), the laboratory failed to monitor freezer temperatures to ensure acceptable reagent storage temperatures were maintained for 21 of 21 months from 01/25/2024 to date of survey. Findings include: 1. On the day of survey, 11/14/2025 at 12:29 pm, during the tour of the laboratory, the surveyor observed the following reagents stored in the laboratory freezer: - Bio-Rad Liquichek Tumor Marker Control. Storage requirements -20C to -70C. - Vitros Na slides. Storage requirements less than or equal to -18C. - Vitros Mg slides. Storage requirements less than or equal to -18C. - Vitros Glu slides. Storage requirements less than or equal to -18C. - Vitros UREA & CREA slides. Storage requirements less than or equal to -18C. - Vitros FE slides. Storage requirements less than or equal to -18C. - Vitros LDHI slides. Storage requirements less than or equal to -18C. - Vitros Calibrator Kit 1. Storage requirements less than or equal to -18C. - Vitros

	Performance Verifier II. Storage requirements less than or equal to -18C. - Vitros Calibrator Kit 4. Storage requirements less than or equal to -18C. 2. Review of the laboratory's temperature records revealed the laboratory's established freezer temperature range (less than or equal to -10 C) failed to ensure acceptable reagent storage temperatures were maintained for 21 of 21 months from 1/25/2024 to 11/14 /2025. 3. The TC (CMS 209 personnel #2, dated 11/06/2025) confirmed the findings above on 11/14/2025 at 1:30 pm. Repeat deficiency**
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's verification of performance specifications records, lack of documentation, and interview with the Technical Consultant (TC), the laboratory failed to verify the required performance specifications for chemistry testing performed on 1 of 1 Tosoh chemistry analyzer and 2 of 2 Sysmex XN -530 hematology analyzers before reporting patient test results from 10/15/2024 to date of survey. Findings include: 1. On the day of the survey, 11/14/2025, at 11:22 am, review of the laboratory's verification of performance specifications records revealed the laboratory failed to perform a reference range/normal value study appropriate for the laboratory's patient population before reporting patient test results on the following chemistry and hematology analyzers from 10/15/2024 to 11/14/2025: - 1 of 1 AIA Tosoh chemistry analyzer (S/N 11813906) - 2 of 2 Sysmex XN-530 hematology analyzers (S/N 12566 and 12430). 2. The laboratory could not provide a policy that included the laboratory's criteria to ensure a reference range/normal value study was appropriate for the laboratory's patient population. 3. The TC revealed during interview, 11/14/2025, the laboratory performed 14,366 tests on the AIA Tosoh chemistry analyzer and 249,940 hematology tests on the Sysmex XN-530 hematology analyzers from 4/28/2025 to 9/30/2025. 4. The TC (CMS 209 personnel #2, dated 11/06/2025) confirmed the findings above on 11/14/2025 at 1:30 pm.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: A. Based on lack of documentation, and interview with the Technical Consultant (TC), the laboratory failed to ensure maintenance/function checks were performed as defined by the manufacturer for 1 of 3 pipettes used for Chemistry testing in the laboratory from 1/25/2024 to 11/14/2025. Findings include: 1. On the day of the survey, 11/14/2025 at 12:15 pm, the laboratory failed to provide documentation of

	maintenance/function checks performed for the following 1 of 3 pipettes used from 1 /25/2024 to 11/14/2025: - Pipette RU24480, Calibration due date 08/2024. 2. The TC (CMS 209 personnel #2, dated 11/06/2025) confirmed the findings above on 11/14 /2025 at 1:30 pm. B. Based on lack of documentation, and interview with the Technical Consultant (TC), the laboratory failed to ensure maintenance/function checks were performed as defined by the manufacturer for 3 of 3 traceable thermometers used to ensure acceptable reagent storage temperatures were maintained in the laboratory from 1/25/2024 to 11/14/2025. Findings include: 1. The laboratory failed to provide documentation of maintenance/function checks performed for the following 3 of 3 traceable thermometers used to monitor temperatures in the laboratory from 1/25/2024 to 11/14/2025: - McKesson freezer thermometer S/N 45753, Calibration due date 12/06/2024. - Traceable refrigerator thermometer "A", Calibration due date 02/2025. - Traceable room temperature thermometer "B", Calibration due date 02/2025. 2. The TC (CMS 209 personnel #2, dated 11/06/2025) confirmed the findings above on 11/14/2025 at 1:30 pm. Repeat deficiency**
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with the Technical Consultant (TC), the laboratory failed to evaluate twice a year the relationship between test results using different instruments for 2 of 2 Sysmex XN-530 hematology analyzers used to perform complete blood cell count (CBC) examinations in 2025. Findings include: 1. On the day of the survey, 11/14/2025 at 11:35 am, the laboratory failed to provide documentation for the comparison of test results (CBC) between 2 of 2 Sysmex XN-530 hematology analyzers (S/N 12566 and S/N 12430) used to perform CBC examinations in 2025. 2. The TC (CMS 209 personnel #2, dated 11/06/2025) confirmed the findings above on 11/14/2025 at 1:30 pm.
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 lack of documentation and interview with the Technical Consultant (TC), the TC failed to assess the competency of 1 of 27 Testing Personnel (TP) that performed chemistry testing in 2024. Findings include: 1. On the day of survey, 11/24 /2025 at 10:07 am, the laboratory failed to provide annual competency assessment records for 1 of 27 TP (CMS 209 TP#2, dated 11/06/2025) that performed chemistry testing in 2024. 2. The laboratory performed 340,618 chemistry examinations in 2024 (CMS 116, estimated annual volume, dated 11/05/2025). 3. The TC (CMS 209

	personnel #2, dated 11/06/2025) confirmed the findings above on 11/14/2025 at 1:30 pm. Repeat deficiency**