Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0187805	05/12/2022
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
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: A. Based on review of the Laboratory's competency policy, competency assessment records and interview with the Technical Consultant (TC), the laboratory failed to establish a competency assessment procedure to assess the competency of 1 of 1 Technical Consultant (TC) (on the CMS 209 form, listed as personnel #2) for their supervisory responsibilities from 01/23/2020 to 05/12/2022. Findings include: 1. On the day of survey, 05/12/2022 at 09:32 am, the TC could not provide a competency assessment policy that reviews how to assess the competency for 1 of 1 TC for their supervisory responsibilities in 2020 and 2021. 2. The TC could not provide competency assessment records for 1 of 1 TC for their supervisory responsibilities. 3. The TC confirmed the findings above on 05/12/2020 around 10:15 a.m. B. Based on review of Laboratory's competency policy and interview with the Technical Consultant (TC), the laboratory failed to establish a competency assessment procedure that includes the six point of CLIA to assess 22 of 22 Testing Personnel (TP) who performed Hematology, Routine Chemistry and Endocrinology examinations from 01 /23/2020 to 05/12/2022 . Findings include: 1. On the day of survey, 05/12/2022 at 09: 32 am, the TC could not provide a competency assessment procedure that includes the six points of CLIA for 22 of 22 TP who performed Complete Blood Count (CBC) (Sysmex analyzer), routine Chemistry (Vitros Ortho Clinical Diagnostic Analyzer), endocrinology (TOSOH), and Serum Human Gonadotropin (Hcg) kit examinations from 01/23/2020 to 05/12/2022. 2. The TC confirmed the findings above on 05/12 /2020 around 11:30 a.m.

D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 Ortho Clinical diagnostics analyzer validation records and interview with Technical consultant (TC), the laboratory failed to establish criteria for acceptable performance specifications for the Vitros Ortho Clinical diagnostics analyzer Validation used for routine chemistry specimens from November 16, 2020 to May 12, 2022. Findings Include: 1. On the day of survey, 05/12/2022 at 10:34 am, review of the Vitros Ortho Clinical diagnostics Validation records revealed, the validation performed on 11/16/2020 did not include criteria for acceptable precision, accuracy, and reportable range. 2. The laboratory analyzed 30,249 test were analyzed on the Vitros Ortho Clinical diagnostics analyzer. 3. TC confirmed the findings above on 05/12/2022 around 11:30 a.m.
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 review of the Vitros Ortho Clinical Diagnostic analyzer validation records and interview with the Technical Consultant (TC), the Laboratory Director failed to approve the performance specifications of precision and accuracy for the chemistry analytes performed on the Vitros Ortho Clinical Diagnostic analyzer used from 11/16/2020 to 05/12/2022. Finding Include: 1. On the day of survey, 05/12/2022 at 10:31 am. record review revealed that the LD did not approve and review the validation for the Vitros Ortho Clinical Diagnostic performed on 11/16/2020. 2. The TC confirmed the finding above on 05/12/2022 at 11:30 a.m.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of Medical Laboratory Evaluation (MLE) Proficiency Testing (PT) records and interview with the Technical Consultant (TC), the laboratory director failed to ensure an approved corrective action plan was documented for the unsatisfactory result for the 2 of 6 MLE events for Chemistry in 2020 and 2021. Findings include: 1. On the day of survey, 05/12/2022 at 09:53 am, review of MLE PT records revealed, the laboratory did not document a correction action plan for the following MLE events: 2020: - Event 3: alanine aminotransferase (ALT) , score of 80%. 2021: - Event 1: thyroid stimulating hormone (TSH), score of 80%. 2. The TC confirmed the findings above on 05/12/2022 at 11:30 am.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory personnel records and interview with the Technical Consultant (TC), the laboratory director (LD) failed to specify, in writing, the responsibilities and duties for 1 of 1 Technical Consultant (TC) engaged in the performance of pre analytical, analytical and post analytic phases of testing from 01/23 /2020 to the day of survey. Findings include: 1. On the date of survey, 05/12/2022 at 09:32 am, The laboratory could not provide the following documentation for 1 of 1 TC: - Documentation of written responsibilities. - Competency assessment records for his responsibilities as a TC. 2. The TC confirmed the findings above on 05/12/2021 around 11:30 am.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the Technical Consultant (TC), the Technical Consultant failed to ensure that 3 of 22 testing

	personnel (TP) received regular in-service training for Hematology and Chemistry tests performed as required from 11/16/2020 to the day of survey. Findings include: 1. At the time of survey,05/12/2022 at 09:20 am, the laboratory was unable to provide training records for 2 of 22 TP (CMS 209 Personnel #17 and #23) who performed Complete blood Count (CBC) tests from January, 2022 to May 12, 2022. 2. The laboratory was unable to provide training records for 1 of 22 TP (CMS 209 Personnel #3) who performed routine chemistry tests on the Vitros Ortho Clinical Diagnostics from 11/16/2020 to 05/12/2022 3. The TC confirmed the findings above on 05/12 /2022 around 11:30 am.
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 lack of competency assessment (CA) records and interview with the Technical Consultant (TC), the technical consultant failed to assess te competency of 6 of 22 Testing Personnel (TP) for Hematology, routine chemistry, and endocrinology examinations in 2020 and 2021. Finding Include: 1. On the day of survey, 05/12/2022 at 09:20 a.m., The TC could not provide CA records for 6 of 22 TP (CMS 209 personnel #2, #3, #4, #10, #12, and #14) who performed complete blood count (CBC) (sysmex analyzer) examinations in 2020 and 2021. 2. The TC could not provide competency assessment records for 2 of 2 TP (CMS 209 personnel #2, and #33) who performed Routine Chemistry (Vitros Ortho Clinical Diagnostics analyzer), Endocrine (TOSOH analyzer), and Serum Pregnancy (McKesson Kit) in 2020 and 2021. 3. The TC confirmed the findings above on 12/08/2021 at 03:00 p.m.