Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0277889	06/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Oncology Care Partners Of Florida, Llc	3700 Washington St Ste 100, Hollywood, FL	

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
D2122	HEMATOLOGY CFR(s): 493.851(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing records and interview with officer manager (OM), the laboratory failed to have a passing score for the first testing event of 2018 for the specialty of hematology. The findings include Review of API proficiency records revealed that there was 0 % for the White Blood Cell Differential (WBC) and 60 % for Red Blood Cell (RBC) with an overall result of 73 % for the specialty of hematology for the 1st event of 2018. During an interview on 6/18/2018 at 12:30 PM, the OM confirmed that the laboratory failed the event of reference.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on API testing evaluation review and staff interview, it was determined that the

	laboratory had scored 60 % for Red Blood Cell (RBC) and 0 % for White Blood Cell (WBC) Identification (ID) for the first event of 2018 and had no documentation that the laboratory had taken remedial action. The findings include: Review of API testing evaluation for 1st event 2018 revealed a failing score of 73% for the Hematology Specialty O % score for WBC and 60 % for RBC. The PT performance review form showed no signature of the laboratory director and no documentation of the corrective action taken. During and interview on 6/18/2018 at 12:30 PM, the testing personnel A confirmed that the laboratory director failed to sign the PT review form and had no documentation of the remedial action for RBC and WBC failing results for the first event of 2018.
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 review of personnel records from 2016 to 2018 and interview with Office Manager (OM) revealed that none of the annual competency records for testing personnel were available from 2016 to 2018. The findings include: Review of personnel records revealed that there were no competency evaluations for 3 out of 3 testing person available for 2016 to 2018. During an interview on 6/18/2018 at 12:30 PM, with the OM, he confirmed there were no records of annual competency evaluation for testing person for the years of reference
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory 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 general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of quality assurance policy and laboratory records from 2016 to 2018 and interview with Office Manager (OM) revealed that the laboratory failed to document the Quality Assurance (QA) activity during the years 2016, 2017 and 2018. The findings include: Review of quality control records revealed that there was no documentation of the QA activity during the years 2016 to 2018. During an interview on 6/18/2018 at 12:30 PM, with the OM, he confirmed there were no records of QA activity records for the years of reference.
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 Hematology Act Diff user manual review and interview with office manager (OM), the laboratory failed to document room temperature requirement to assure optimal operation of the Hematology Coulter Act diff during 2016, 2017 until June 2018. The findings include: Review of the Coulter manual indicates that the operation temperature range is 16-35 C. There was no temperature log available for documenting the temperature of the laboratory room during 2016, 2017 until June 2018. During an interview on 6/18/2018 at 12:30 p.m., the Office Manager confirmed that there was no documentation of room temperature control during the period of reference.
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 American Proficiency Institute (API) proficiency testing records and interview with officer manager (OM), the laboratory director failed to sign the API PT performance evaluation form for the failure results of red blood cells (RBC) 60 % and white blood cell (WBC) 0 % score test on the first event of 2018 and to document corrective actions for this result. The findings include: Review of API proficiency records revealed that there was unsatisfactory result for RBC of 60 % and 0 % WBC test for the 1st event of 2018. There was no signature of the laboratory director of the form of the performance review and no documentation of the corrective actions performed. During an interview on 6/18/2018 at 12:30 PM, the OM confirmed that the laboratory director failed to sign the results of the event of reference and to document the corrective action for the event of reference. Refer to 2122 and 2128
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 review of quality assurance policy and laboratory records from 2016 to 2018 and interview with Office Manager (OM) revealed that the laboratory director failed to doccument the review of quality assurance (QA) activity during the years 2016, 2017 and 2018. The findings include: Review of quality control records revealed that there was no documentation of the QA activity during the years 2016 to 2018. During an interview on 6/18/2018 at 12:30 PM, with the OM, he confirmed there were no records of QA activity for the years of reference. Refer to 5293
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 personnel records from 2016 to 2018 and interview with Office Manager (OM) revealed that the laboratory failed to perform annual competency evaluation for the testing personnel for 2016, 2017 and 2018. The findings include: Review of personnel records revealed that there were no annual competency evaluations for 3 out of 3 testing person during the years 2016 to 2018. During an interview on 6/18/2018 at 12:30 PM, with the OM, he confirmed there were no records of annual competency evaluation for testing person for the years of reference. Refer to 5209