Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0277889	01/28/2020
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
D0000	An announced CLIA recertification survey was conducted at Calvin S. Rosenfeld MD PA DBA Oncology Associates on 01/28/2020. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D5200-General Laboratory Systems- 493.1230 D5400-Analytic Systems- 493.1250
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Manager the laboratory failed to retain QC (Quality Control) records for at least 2 years. Findings Included: Review of QC results revealed no records prior to 12/27/2018. Interview 01/28/2020 at 4:11 PM the Laboratory Manager confirmed that there were no QC records prior to 12/27/2018.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.

	This CONDITION is not met as evidenced by: Based on record review and interview with the Laboratory Manager the laboratory failed to have competency evaluations on 2 (#A and #B) out of 2 Testing Personnel (See D5209) and the laboratory failed to have any QA (Quality Assurance) records (D5293).
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 Laboratory Manager the laboratory failed to have competency evaluations on 2 (#A and #B) out of 2 Testing Personnel. This is a repeat deficiency from the 06/18/2018 recertification survey. Findings Included: Review of the CMS 209 (signed by the Laboratory Director 01/27/2020) revealed that there were 2 Testing Personnel. Review of the employee files revealed no competency evaluations for Testing Personnel #A or #B. Interview on 01/28/2020 at 2:49 PM the Laboratory Manager confirmed that there were no competency evaluations for Testing Personnel #A and #B. Review of the plan of correction from the recertification survey conducted on 06/18/2018 (signed by the Laboratory Director on 07/31/2018) revealed that this deficiency was corrected on 06/22/2018 by the Laboratory Director and that "The lab director is responsible for all corrective action."
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 record review and interview with the Laboratory Manager the laboratory failed to have any QA (Quality Assurance) records. This is a repeat deficiency from the 06/18/2018 recertification survey. Findings Included: Review of laboratory records revealed no QA records. Interview on 01/28/2020 at 4:11 PM the Laboratory Manager confirmed that no QA had been documented. Review of the plan of correction from the recertification survey conducted on 06/18/2018 (signed by the Laboratory Director on 07/31/2018) revealed that this deficiency was corrected on 06/22/2018 by the Laboratory Director and that "The lab director is responsible for all corrective action."
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 record review and interview with the Laboratory Manager the laboratory failed to record the room temperature where complete blood count (CBC) testing was being performed (See D5413) and the laboratory failed to monitor quality control (QC) over time for shifts and trends for 2 (2018-2020) out of 2 years reviewed (See D5441).
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Manager the laboratory failed to monitor quality control (QC) over time for shifts and trends for 2 (2018-2020) out of 2 years reviewed. Findings Included: Review of QC records reveled only daily QC. There was no documentation of monitoring the shifts and trends of the QC over time. Interview on 01/28/2020 at 3:30 PM the Laboratory Manager confirmed that they did not have a system in place to monitor shifts and trends of the QC over time.
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 record review and interview with the Laboratory Manager the laboratory failed to record the room temperature where complete blood count (CBC) testing was being performed. This is a repeat deficiency from the 06/18/2018 recertification survey. Findings Included: Review of temperature logs revealed that the room temperature was not being recorded. Interview on 01/28/2020 at 4:11 PM the Laboratory Manager confirmed that the room temperature was not being recorded. Review of the plan of correction from the recertification survey conducted on 06/18 /2018 (signed by the Laboratory Director on 07/31/2018) revealed that this deficiency

	was corrected on 06/22/2018 by the Laboratory Director and that "The lab director is responsible for all corrective action."