Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0277889	03/16/2022
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	A recertification survey was conducted on March 16, 2022. GenesisCare USA of Florida LLC clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories. The following Condition was not met: D6000 - Moderate Complexity Laboratory Director
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director and Testing Personnel failed to have documentation of the signing of the attestation form for proficiency testing (PT) for two (2021 2nd, 3rd event) of six (2020 1st, 2nd, 3rd & 2021 1st, 2nd, 3rd events) for the specialty of hematology. Findings: Review of the American Proficiency Institute (API) Attestation Statement noted "Signatures Required - Testing personnel and laboratory director must physically sign an attestation statement for PT results, and retain the signed statement (or a copy) for a minimum of 2 years." Review of the API PT records showed that the signing of the attestation statement for the 2nd and 3rd events in 2021 were missing. On 03/16/2021 at 1:53 PM, Laboratory Consultant acknowledge the attestations signatures were missing
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the

	proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have maintain copies of the testing results (instrument printouts) from the proficiency testing (PT) for two (2021 2nd, 3rd) of six (2020 1st, 2nd, 3rd & 2021 1st, 2nd, 3rd) events for the specialty of hematology. Findings: Review of the American Proficiency Institute (API) PT records showed the instrument printouts from the Beckman Coulter AcT 5diff hematology analyzer for the 2nd and 3rd events in 2021 were missing. On 03/16 /2021 at 1:53 PM, Laboratory Consultant stated she did not know where the instrument printouts were located.
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, the laboratory failed to retain Quality Control (QC) documents from 01/28/2020 to 12/22/2020. This is a repeat deficiency for the recertification survey performed on 01/28/2020. Findings: 1. Review of QC for the daily controls (low, normal, high) run on the Beckman Coulter AcT 5diff hematology analyzer revealed there were no records available for review before 12/22/20. Review of the QC for the daily controls from 11/05/2021 to 01/04/2022 revealed the laboratory only had documentation of the low level (lot #361121) and normal level (lot #371121) controls. Documentation of the high level control was not available for review. On 03/16/2022 at 2:41 PM the Laboratory Consultant stated she did not know where the QC records were. 2. Review of the hematology analyzer's background counts revealed there were no records before 12/01/2020. On 03/16/2022 at 2:41 PM the Laboratory Consultant stated she did not know where the QC records were. 3. According to the Coulter AcT 5diff Control Plus hematology daily controls must be store at a temperature of 2 - 8 degrees Celsius. Review of the laboratory's refrigerator temperature records revealed there were no logs available for review from 01/29/2020 to 01/05/22. On 03/16/2022 at 4:10 PM the Laboratory Consultant stated she did not know where the refrigerator temperature log were.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

	This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director failed to document the review and evaluation of proficiency testing (PT) for two (2020 2nd, 2021 1st) of six (2020 1st, 2nd, 3rd & 2021 1st, 2nd, 3rd) events for the specialty of hematology. Findings: Review of the American Proficiency Institute (API) PT showed the Laboratory Director failed to sign the "Proficiency Testing Performance Evaluation" forms for the 2nd event in 2020, and the Performance Review and the Corrective Action documentation for the 1st event in 2021. On 03/16/2021 at 1:53 PM, Laboratory Consultant acknowledged the Laboratory Director had not signed the performance reviews or the corrective action.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on record review, observation, and interview, the laboratory failed to label the quality control vials currently in use with the expiration date from 03/03/2022 to 03/16 /2022. Findings: Review of the product information sheet for the "Coulter AcT 5diff Control Plus" noted, "Open vial stability 15 days." Observations on 03/16/2022 at 1: 30 PM of the box with the controls showed the box was opened on 03/03/2022. Observations on 03/16/2022 at 1:32 PM of the low, normal, and high control vials showed the vials did not have an open or expiration date written on the vials currently being used. On 03/16/2021 at 1:33 PM, Laboratory Consultant stated the opened expiration date were not listed on the control vials.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to provide all required information on the test reports given to patients for five of five sampled patients, (#1, #2, #3, #4, #5). Findings: Review of the hematology instrument printout that is given to patients who request a copy of their laboratory results revealed the name of the laboratory as it appeared on the CLIA (Clinical Laboratory Improvement

	Amendments) Certificate is not on the printout. On 03/16/2022 at 3:57 PM, the Administrator stated they gave a copy of the instrument printouts to patients if they requested it, and that laboratory's name is not on the report.
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 and staff interview, the Laboratory Director failed to provide overall management and direction of the laboratory. Cross Reference D6020: Based on record review and interview, the Laboratory Director failed to ensure the quality control program was maintained to assure the quality of laboratory services provided from 01/28/2020 to 12/22/2020.
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: Based on record review and interview, the Laboratory Director failed to ensure the quality control program was maintained to assure the quality of laboratory services provided from 01/28/2020 to 12/22/2020. Findings: The Laboratory Director failed to ensure the laboratory failed to retained Quality Control (QC) documents from 01/28 /2020 to 12/22/2020. This is a repeat deficiency for the recertification survey performed on 01/28/2020. (See D3031)
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 record review and interview, the Technical Consultant (Laboratory Director) failed evaluate the competency of testing personnel listed on the Laboratory's Personnel Report for two of two personnel (A, B) for 2021. Findings: Review of the Laboratory Personnel Report, signed by the Laboratory Director on 03/09/2022 showed there are three employees listed on the form, two Testing Personnel and the Laboratory Director. The Laboratory Director is also listed as the Clinical Consultant

	and the Technical Consultant. Review of the Testing Personnel A's competency evaluation for 2021 showed it was signed by the Laboratory Consultant. Review of the Testing Personnel B's competency evaluation for 2021 showed it was signed by the Administrator. On 03/16/2020 at 2:26 PM, Laboratory Consultant acknowledged the competency evaluations were not signed by the Laboratory Director.