Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 10D2126717	**(X3) Date Survey Completed** 07/09/2020
Name of Provider or Supplier Genesiscare Usa Of Florida Llc	**Street Address, City, State** 601 Redstone Avenue West, Crestview, 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 21st Century Oncology LLC on July 9, 2020. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of CMS 209- Laboratory Personnel Report, review of American Proficiency Institute (API) proficiency testing, and interview with the Laboratory Staff, the laboratory failed to have all testing personnel to rotate the proficiency testing for the specialty of Hematology for 1 of 2 years reviewed (2019-2020). Findings Included: Review of the CMS 209 (signed and dated by the Laboratory Director 07/06//20) had 3 testing personnel listed (#2 - #4). Review of API proficiency testing for the specialty of Hematology found that there was only one testing person (# 2) who performed the proficiency testing in 3 of 3 events of 2019 through 1 of 1 event of 2020. Interview with the Laboratory Staff (testing person # 2) on 07/09/20 at 11:00 AM confirmed that Testing Person #2 was the only person performing proficiency testing even though Testing Person #2 - #4 all performed patient testing.
D2127	HEMATOLOGY CFR(s): 493.851(d) Failure to return proficiency testing results to the proficiency testing program within

	the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on record review of American Proficiency Institute (API) Hematology proficiency testing results and interview with the Laboratory Staff, the laboratory failed to submit the laboratory's proficiency testing results in the specified timeframe for the 2nd Hematology Event in 2019, resulting in a score of 0% for all Hematology analytes. Findings included: Review of the API Hematology proficiency testing results revealed that the laboratory had obtained a score of 0% for Hematology, Cell Identification or WBC (White Blood Cell) Differential, Red Blood Cell, Hematocrit, Hemoglobin, WBC and Platelets for the 2nd Hematology Event of 2019. Interview on 07/09/20 at 10:30 AM, the Laboratory Staff (testing person # 2) confirmed that the proficiency testing results were sent to API but the laboratory was not aware that the results were not received by the API for the 2nd Hematology Event in 2019.