Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0267170	09/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Genesiscare Usa Of Florida, Llc	425 North Lee St, Ste 104, Jacksonville, 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	At the time of the announced, onsite initial survey, 21st Century Oncology Llc was found to not be in compliance with the CLIA laboratory requirements of 42 CFR 493
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory was not enrolled in proficiency testing (PT) for the specialty of Hematology for 2019. Findings include: At the time of survey, the laboratory was unable to provide documentation to show enrollment in proficiency testing. The interview with the Office Manager at 10:50 a.m. on September 23, 2019 confirmed that the laboratory did not have documentation to indicate PT enrollment or testing. Testing performed under this specialty includes Complete Blood Count.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242.

	This STANDARD is not met as evidenced by: Based on lack of records and staff interview, the laboratory did not have a written quality assessment (QA) policy for preanalytic systems. Findings include: At the time of survey, the laboratory was unable to provide documentation of a QA policy. The interview with the Office Manager at 10:30am on 9/23/19 revealed there was no quality assessment policy to monitor, assess, and correct problems identified in preanalytic systems.
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 review of the laboratory's lack of records and staff interviews, the laboratory failed to have a procedure manual signed by the laboratory director (refer to D5401); failed to establish a quality control procedure (refer to D5441); and failed to have a quality assessment procedure in place for analytic systems (refer to D5791). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results. .
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have a procedure manual. Findings include: At the time of survey, the laboratory was unable to show documentation of a procedure manual reviewed and signed by the Laboratory Director. The interview with the Office Manager on 9/23/19 at 10:45am confirmed no procedure manual had been written.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1)

	Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish a quality control (QC) procedure for how it verified the accuracy and precision of the Complete Blood Count testing performed on patient samples. Findings include: At the time of survey, the laboratory was unable to provide a QC procedure. The interview with the Office Manager on 9/23/19 at 10:30am confirmed no QC procedure was in place.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on lack of records and staff interview, the laboratory did not have a written quality assessment (QA) policy for analytic systems. Findings include: At the time of survey, the laboratory was unable to provide documentation of a QA policy. The interview with the Office Manager at 10:30am on 9/23/19 revealed there was no quality assessment policy to monitor, assess, and correct problems identified in analytic systems.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on lack of records and staff interview, the laboratory did not have a written quality assessment (QA) policy for post-analytic systems. At the time of survey, the laboratory was unable to provide documentation of a QA policy. The interview with the Office Manager at 10:30am on 9/23/19 revealed there was no quality assessment policy to monitor, assess, and correct problems identified in post-analytic systems.
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 sufficient over sight of the laboratory's testing process. The findings include: 1. The Laboratory Director failed to ensure that the laboratory was enrolled in proficiency testing . Refer to D6015. 2. The Laboratory Director failed to establish a quality control (QC) program. Refer to D6020. 3. The Laboratory Director failed to establish and follow a quality assurance program. Refer to D6021. 4. The Laboratory Director failed to ensure the laboratory had a process in place to evaluate personnel competency of the staff performing moderate complexity testing. Refer to D6030. 5. The Laboratory Director failed to ensure a procedure manual was in place and available to all testing personnel. Refer to D6031. .
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure that the laboratory was enrolled in proficiency testing with an approved proficiency testing program in 2019. Findings include: An attempt to review the laboratory's proficiency testing revealed that no documentation of proficiency testing was available for inspection. The laboratory performs testing on the following analytes: Erythrocytes Count (RBC), Hematocrit, Hemoglobin, Leukocyte Count (WBC), and Platelet Count. During an interview on 9/23/19 at 10:50 AM, the Office Manager stated they were not enrolled in proficiency testing with an approved proficiency testing company.
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 with the Office Manager, the Laboratory Director failed to identify that the laboratory failed to establish a quality control (QC) program. Findings include: At the time of survey, the laboratory was unable to provide a QC procedure. The interview with the Office Manager on 9/23/19 at 10: 30am confirmed no QC procedure was in place.
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 record review and staff interview, the Laboratory Director failed to establish and follow a quality assurance program. Findings included: At the time of survey, the laboratory was unable to provide documentation of a Quality Assurance program. The interview with the Office Manager on 9/23/19 at 10:45am revealed that there was no quality assessment policy to monitor, assess, and correct problems identified in pre-analytic, analytic, and post-analytic systems. .
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to ensure a personnel competency program was in place to evaluate staff competency. Findings include: The facility was unable to provide documentation of a competency program approved by the Laboratory Director and performed by a Technical Consultant for personnel performing laboratory testing for Complete Blood Count. The interview with the Office Manager on 9/23/19 at 10:15am confirmed that no competency program with Technical Consultant over sight was in place for laboratory personnel. .
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

	This STANDARD is not met as evidenced by: Based on the lack of a procedure manual and staff interview, the Laboratory Director failed to ensure a procedure manual was in place and available to all testing personnel. Findings include: At the time of survey, the laboratory was unable to show documentation of a procedure manual reviewed and signed by the Laboratory Director. The interview with the Office Manager on 9/23/19 at 10:45am confirmed no procedure manual had been written.