

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2167889	(X3) Date Survey Completed 11/12/2019
Name of Provider or Supplier Genesiscare Usa Of Florida, Llc	Street Address, City, State 3651 Fau Blvd Ste 100, Boca Raton, 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 initial certification survey conducted on 11-12-19, found that 21st Century Oncology LLC /DBA/ Florida Precision clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D2128	<p>HEMATOLOGY CFR(s): 493.851(e)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing record review and staff interview, the laboratory failed to receive a passing score of 80 percent for the White Blood Cell Differential analyte for the second event of American Proficiency Institute (API) in 2019. Findings included: A review of the API proficiency testing record indicated the laboratory received a score of 28 percent for the White Blood Cell Differential analyte for the second event on June 23rd, 2019. On 11-12-19 at 12:00pm, The testing person A and office manager confirmed that the laboratory had received a score of 28 percent for the White Blood Cell Definitely analyte for the 2nd event in 2019.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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,</p>

consultant competency.

This STANDARD is not met as evidenced by:

Based on record review and interviews, the laboratory failed to provide an initial competency assessment for 1 out of 1 testing persons (TP)(#A) in 2019. Findings included: A review of the CMS 209 Laboratory Personnel form, indicated the TP#A was a testing person in 2019. A review of the testing personnel competency record revealed that TP# A had no initial competency completed in between June - October 2019. During interview on 11-12-19 at 12:00pm, testing person A and office manager confirmed that no initial competency was not done for TP#A in 2019.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory director failed to provide job description policies for 4 out of 4 (testing personnel (TP), technical consultant (TC), clinical consultant (CC) and laboratory director (LD) positions in the procedure manual for 2019. Findings included: A review of Procedure Manual record revealed missing job description policies for TP, TC, CC and LD. During interview on 11-12-2019 at 12:00pm, testing person A and office manager confirmed that job description policies were missing for Testing Personnel, Technical Consultant, Clinical Consultant and Laboratory Director in the procedure manual.