Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0267170	02/15/2022
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	A desk review survey of the laboratory's proficiency test results was performed on February 15, 2022 for GenesisCare USA of FL, LLC. The GenesisCare USA of FL, LLC laboratory is not in compliance with Code of Federal Regulations (CFR), Part 493, Laboratory Requirements
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the laboratory's proficiency testing records for 2021, the laboratory did not have successful performance in proficiency testing in the specialty of hematology. Refer to D 2130. Findings include: Review of the American Proficiency Institute (API) proficiency testing records and the review of the Centers

	for Medicare & Medicaid Services (CMS) 153 and 155 reports, on February 15, 2022 on or about 10:00 AM, showed that the laboratory had unsatisfactory testing scores for the analyte, white blood cell differential for two consecutive testing events in 2021.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on the review of the Centers for Medicare & Medicaid Services (CMS) 153 and 155 reports and the laboratory's proficiency testing records, the laboratory did not have successful performance in proficiency testing in the specialty of hematology. Findings include: On February 15, 2022, on or about 10:00 AM the American Proficiency Institute (API) proficiency testing records and the CMS 153 and 155 reports were reviewed. The review showed that the laboratory failed to achieve satisfactory performance for the analyte, white blood cell differential, as shown below. Event #2, 2021 white blood cell differential-73% Event #3, 2021 white blood cell differential-53%
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 the review of the laboratory's proficiency testing records, the laboratory director failed to ensure that the laboratory maintained a satisfactory score for proficiency testing in the specialty of hematology. Findings include: On February 15, 2022, on or about 10:00 AM, the American Proficiency Institute (API) proficiency records and the Centers for Medicare & Medicaid Service (CMS) 153 and 155 reports were reviewed. The review showed that the laboratory had unsatisfactory testing scores for two consecutive testing events for the analyte, white blood cell differential, in the specialty of hematology. The laboratory director is responsible for ensuring that the laboratory maintains successful participation in proficiency testing. Refer to D 2130.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

	This STANDARD is not met as evidenced by: Based on the review of the laboratory's proficiency testing scores, the laboratory director failed to ensure that the laboratory performed proficiency testing in such a manner as to achieve and maintain successful participation in proficiency testing in the specialty of hematology. Findings Include: The review of the American Proficiency Institute (API) proficiency testing records and the Centers for Medicare & Medicaid Services (CMS) 153 and 155 reports on February15, 2022 on or about 10:00 AM showed that the laboratory received unsatisfactory proficiency testing scores for two consecutive testing events as shown below. Event #2, 2021 white blood cell differential-73% Event #3, 2021 white blood cell differential-53%