Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0267170	05/12/2021
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 recertification survey, Genesiscare USA of Florida, Llc was found to not be in compliance with the CLIA laboratory requirements of 42 CFR 493. .
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 review of proficiency testing records and interview with staff, the Laboratory Director or designee failed to sign proficiency test attestation statements for 4 of 5 testing events reviewed. The findings include: Review of American Proficiency Institute (API) Hematology test records showed the Laboratory Director or designee failed to sign API's attestation statements attesting to the routine integration of the proficiency samples into the patient workload using the laboratory's routine methods for the following testing events: a. 2020 - Event 1, Event 2, and Event 3 b. 2021 - Event 1 During interview on 5/12/21 at 11:00 AM, the testing person confirmed the attestation statements listed above were not signed by the Laboratory Director or designee. .
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples.

	This STANDARD is not met as evidenced by: Based on review of proficiency test records and interview with staff, the laboratory failed to test proficiency samples the same number of times that patient samples are tested for 1 of 5 testing events reviewed. The findings include: A review of 2020's 3rd event American Proficiency Institute (API) proficiency documentation showed testing of the five proficiency samples was performed twice on 11/19/2020. The tests performed were: White Cell Count, Red Cell Count, Hemoglobin, Hematocrit, Platelet Count, Mean corpuscular volume (MCV), Red cell distribution width (RDW), Lymphocytes, Granulocytes, Mean corpuscular hemoglobin (MCH), Mean corpuscular hemoglobin concentration (MCHC), and Mean platelet volume (MPV). HEM 11 - Tested on 11/19/20 at 2:43 PM and 3:10 PM HEM 12 - Tested on 11/19/20 at 2:46 PM and 3:12 PM HEM 13 - Tested on 11/19/20 at 2:47 PM and 3:19 PM HEM 14 - Tested on 11/19/20 at 2:49 PM and 3:22 PM HEM 15 - Tested on 11/19/21 at 2:50 PM and 3:24 PM Interview with the testing person on 5/12/21 at 11:00 AM confirmed hematology proficiency testing had been performed in duplicate to make sure the answers were correct. It was further confirmed that patients are not tested in duplicate. .
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 staff interview, the laboratory failed to retain the Cell-Dyn 1800 instrument reports for their proficiency testing results for 3 of 5 events reviewed in 2019 and 2020. The findings include: A record review of the American Proficiency Institute (API) proficiency test events showed that no records from the instrument (Cell-Dyn 1800) used to perform the Complete Blood Count (CBC) was maintained for the following events: a. 2019 Event 3 b. 2020 Event 1 and Event 2 An interview with the testing person on 5/12/21 at 11:30am confirmed that the records from the Cell-Dyn 1800 were not kept. .
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility failed proficiency testing for the analytes of Leukocyte Count and White Blood Cell Differential in the specialty of

	Hematology for the second event of 2020. The findings include: The 5/12/21 record review of the API proficiency scores for Event 2 of 2020 showed the facility scored a 60% for Leukocyte count, an overall score of 47% for the White Blood Cell Differential, which includes a score of 20% for Granulocytes and 20% Lymphocytes. The interview with the testing person on 5/12/21 at 11:00 AM confirmed the proficiency testing failure. .
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on record review and staff interview, the facility failed to ensure that Hematology proficiency testing was evaluated and corrective action taken for unacceptable proficiency results (D5211); failed to ensure competency assessment was performed (D5209); failed to monitor and document room temperature and humidity of the laboratory (D5413) follow manufacturer instructions for monthly maintenance of the Cell-Dyn 1800 (D5429); and failed to provide documentation indicating calibrations were performed every 6 months (D5439). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results. .
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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, consultant competency. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document six month and annual competency assessment for the one testing person for two of two years reviewed (2019-2020). The findings include: Review of annual competency showed initial training was performed on 5/22/19. There was no documentation of a 6-month competency assessment or an annual competency assessment for the one testing person. The interview with the Office Manager on 5/12/21 at 11:30 AM confirmed competency assessment was not performed. .
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 interview, the laboratory failed to document the review and evaluation of proficiency testing (PT) for the 2nd event of 2020 for the specialty

	of hematology. The findings include: Review of the American Proficiency Institute (API) PT showed that the Laboratory Director failed to sign "Proficiency Testing Performance Evaluation and Corrective Action" form for the 2nd event of 2020. During an interview on 5/12/21 at 11:30 AM, the Office Manager acknowledged the Laboratory Director did not sign the evaluation forms. .
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document the room temperature and humidity of the laboratory for two of two years reviewed (2020-2021). The findings include: The Cell-Dyn 1800 Operator's Manual states in Section 2-4, "To ensure the instrument and reagents function properly, it is important to maintain the temperature between 68F and 86F (20C and 30C)", and states humidity must be maintained between 10% and 85%. The laboratory had no documentation showing the room temperature or humidity was being monitored in 2020 or 2021. The interview with the Office Manager on 5/12/21 at 10:40 AM, confirmed the laboratory was not monitoring room temperature or humidity. .
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility failed to ensure the monthly maintenance required for the Cell-Dyn 1800 was performed for one of three months reviewed (December 2020). The findings include; The record review of the "Service and Maintenance" log documentation showed no record of the monthly maintenance of "Rinse Lyse Inlet Lines" and "Rinse Reagent Inlet Lines" being performed in December 2020. The Cell-Dyn 1800 System Operator's Manuel states, "Monthly - Rinse the Lyse Inlet Line -Rinse the Reagent Inlet Line". The interview on 5/12/21 at 10:30 AM with the testing person confirmed the maintenance was not performed. .
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions;

	(b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure that the Cell-Dyn 1800 analyzer was calibrated at a minimum of every 6 months. The findings include: Review of calibration verification records for the hematology analyzer showed that calibration verifications were performed on 6/12/2019 and 5/7/2021. The interview with the Office Manager on 5/12/21 at 10:15 AM confirmed the calibrations records were missing. .
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, there was no documentation to indicate that the director ensured that corrective action was performed when proficiency testing results were unsatisfactory. The findings include: On 5/12/2021, review of proficiency testing records for the past two years revealed that for the second testing event of 2020, the laboratory received an unsatisfactory score of 60% for white blood cells, and an overall score of 47% for White Blood Cell Differential. The API Performance Review/ Corrective Action form and Corrective Action Checklist was not signed by the Laboratory Director or designee. The Corrective Action Checklist did not indicate any findings or corrective action. The interview with the testing person on 5/12/21 at 11:30 AM confirmed the forms were not signed by the laboratory director and further confirmed the only correction action performed was cleaning the Cell-Dyn.