Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0267170	(X3) Date Survey Completed 01/18/2023
Name of Provider or Supplier Genesiscare Usa Of Florida, Llc	**Street Address, City, State** 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. .
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 weekly maintenance was performed on the Cell Dyn Emerald analyzer for 3 of 3 months reviewed (November 22, December 22, January 23). The findings include: The Cell Dyn Emerald Instructions for Use booklet states "Bleach Cleaning the system with a bleach solution is performed weekly and as needed if instrument use conditions cause frequent rejection of measured or quality control material out of range issues". The laboratory was unable to show documented weekly maintenance of the instrument. The interview with Testing Person A on 1/18/23 at 11:00am confirmed weekly maintenance was not documented.