Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 10D2057872	**(X3) Date Survey Completed** 07/09/2021
Name of Provider or Supplier Genesiscare Usa Of Florida, Llc	**Street Address, City, State** 5065 Sr 7 Ste 203, Lake Worth, 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 announced recertification survey was conducted on 7/9/21 at Genesiscare USA of Florida, LLC, a clinical laboratory in Lake Worth, Florida. Genesiscare USA of Florida, LLC is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements. The following Condition was cited: D6076 - 493.1441 Condition: Laboratories performing high complexity testing; laboratory director
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 competency and procedure manual record review and staff interview, the laboratory failed to perform competency assessments on the Testing Personnel (#A) for the one year (2020) out of two years (2019 - 2020). The findings included: A review of the CMS 209 Laboratory Personnel Report revealed Testing Personnel (TP) Staff #A worked at the laboratory in 2019 and 2020. A review of personnel records from 2019 - 2020 revealed TP Staff #A did not have an annual competency evaluation for the year 2020. A review of the Quality Assurance Plan revealed a section "Personnel Assessment" stated " At least annually, the laboratory director will review the performance of each employee working in the laboratory to assure employee competency." In an interview on 7/9/21 at 9:45 a.m., Testing Personnel #A confirmed the laboratory director had not performed her annual competency evaluation in 2020.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other

	supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation and interview with Testing Personnel #A, the laboratory failed to ensure Mueller Hinton Agar plates that are used for bacteriology sensitivity tests were removed from use after the expiration date. The findings included: Direct observation on 7/9/21 at 9:35 a.m., revealed the opened package of Mueller Hinton Agar plates had expired on 6/10/21. Review of Log for Patient Urine Culture and Sensitivity Tests revealed that 10 patients had sensitivity tests performed since 6/10 /21. In an interview on 7/9/21 at 9:40 a.m., Testing Personnel #A stated she had received new lots of Mueller Hinton Agar plates and did not know if she had used the expired Mueller Hinton Agar plates.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with Testing Personnel #A, the laboratory failed to have an acting Laboratory Director. The findings included: The laboratory did not have an acting Laboratory Director (See D6078).
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b) (1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience

	directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on CMS-209 Laboratory Personnel Report, Laboratory Director personnel record review, and staff interview, the laboratory failed to have a Laboratory Director since 7/1/21. The findings included: Review of the previous CMS-209, Laboratory Personnel Report, CMS 116 and Application for CLIA Certification, signed and dated on 4/25/19 revealed Staff B, Medical Doctor (MD), served as the Laboratory Director. Review of a resignation letter, dated 6/21/21 by Staff B, MD, addressed to the Agency Health Care Administration and the lab licensing unit indicated the Laboratory Director's resignation was effective July 1st, 2021. Interview on 7/9/19 at 9:30 a.m., Testing Personnel #A and the Office Manager stated the former Laboratory Director (Staff B, MD) had left the provider on 7/1/21 and no notification of a change in Laboratory Director was ever made. The laboratory ceased moderate and high complexity testing after July 1, 2021.