Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2024106	(X3) Date Survey Completed 03/10/2022
Name of Provider or Supplier Genesiscare Usa Of Florida, Llc	**Street Address, City, State** 10115 Forest Hill Blvd Ste 100, Wellington, 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 3/10/22 at Genesisicare USA of Florida LLC, a clinical laboratory in Boynton Beach, Florida. Genesisicare USA of Florida LLC, is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements. The following Conditions were cited: 493.1250 Condition: Analytic systems 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director The following is description of the Condition and Standard-level noncompliance.
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 American Proficiency Institute (API) proficiency record review,record review of the policy and procedure manual, and interview with the Laboratory Director, the laboratory failed to have documentation of signed attestations for the API Chemistry Core for Prostrate Specific Antigen (PSA) and Testosterone proficiency testing for five proficiency testing events (2020 1st and 2nd Events, and 2021 1st, 2nd, and 3rd Events) out of seven events reviewed. The findings include: Review of API Chemistry Core for PSA and testosterone proficiency records revealed

	that the attestation statements for five proficiency testing events (2020 1st and 2nd Events, and 2021 1st, 2nd, and 3rd Events) out of seven (2020 1st, 2nd, and 3rd Events, 2021 1st, 2nd, and 3rd Events, and 2022 1st Event) had not been signed by the Testing Personnel or the Laboratory Director. Review of the policy and procedure manual revealed, "Ten Steps to Successful Proficiency Testing" 7. Filling out the result form: f. Have the attestation statement signed by the analyst and lab director". On 3/8/22 at 12:20 p.m., the Laboratory Director stated he was unaware the API Chemistry Core proficiency testing attestation statements had not been signed.
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 review of employee competency records and interview with the Laboratory Director, the Laboratory Director failed to perform competency evaluations on one Testing Personnel (#B) of two Testing Personnel (#A and #B) who perform Prostate Specific Antigen (PSA) and Testosterone testing in the subspecialties of Routine Chemistry and Endocrinology for 2 of 2 (2020-2021) years reviewed. The findings include: Review of employee competency records found no competency evaluations performed on Testing Person #B who performed PSA and Testosterone testing for two out of two years (2020 - 2021) Record review of the "Quality Assurance Plan" revealed, "V. Personnel Assessment: At least annually, the laboratory director will review the performance of each employee working in the laboratory to assure employee competency. The written result of the review will be filed in the individual's personnel file." Record review of the "Personnel" procedure revealed, "Technical Consultant: Duties: 9. Evaluating the competency of all testing personnel is made". Review of the CMS 209 signed by the Laboratory Director and dated 3/7/22 revealed the Laboratory Director was also the Technical Consultant. On 3/8/22 at 10:00 a.m., the Laboratory Director stated the laboratory did competencies every year or 2. He added that they probably didn't do competency evaluations for 2020 and 2021 due to COVID.
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 review of American Proficiency Institute (API) proficiency testing, and interview with the Laboratory Director, the Laboratory Director failed to document the review of the API Chemistry Core proficiency testing for Prostrate Specific Antigen and Testosterone for 6 (2020 1st, 2nd, and 3rd Events and 2021 1st, 2nd, and 3rd Events) out of 6 testing events reviewed. The findings include: Review of API Chemistry Core proficiency testing records for the 2020 1st, 2nd, and 3rd and 2021 1st, 2nd, and 3rd testing events revealed that the laboratory did not have documentation that the results were reviewed by the Laboratory Director. On 3/8/22 at

	12:35 p.m., the Laboratory Director confirmed he had not documented his review of the proficiency testing results.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview with the Laboratory Director , the laboratory failed to have the laboratory's procedure manual signed by the current laboratory director (see D5407), and failed to follow written policies and procedures to monitor and assess, and to correct problems according to the Individualized Quality Control Plan (see D5791)
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and interview the Laboratory Director did not approve, sign, and date the policies and procedures when he became Laboratory Director on 12/23 /2015. The findings include: Review of the Change in Laboratory Director paperwork revealed the new Laboratory Director was effective on 12/23/2015. Review of the policy and procedure manual revealed the new Laboratory Director had not approved, signed, and dated the policies and procedures. On 3/8/22 at 12:45 p.m., the Laboratory Director stated he was not aware the policy and procedures had not been signed.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of the Individualized Quality Control Plan (IQCP) records and interview with Laboratory Director, the laboratory failed to monitor and assess room temperature and humidity where Prostate Specific Antigen (PSA) and Testosterone testing was performed for two out two years (2020 - 2022), and failed to monitor the freezer temperature where the quality controls for PSA and Testosterone were stored for two out two years(2020 - 2022) as stated in the Nanoentek Frend System IQCP.

	The findings include: A review of the IQCP risk assessment for the Nanoentek Frend showed the following: "Target Failure Mode - Incorrect results due to use of deteriorated reagents - The QCP Actions Required to Address Known Limitations - Laboratory - Implemented control processes: monitor storage conditions or use continuous temperature monitoring." "Target Failure Mode - Incorrect results due to operating the measuring system outside of manufacturer's environmental specifications: Monitor room temperature and humidity- Use automated environmental monitoring for outpatient clinic." Record review of the Nanoentek Frend User Manual revealed "Operating condition: Temperature 15 - 30 degrees Celsius, Humidity: 10% - 80%". Record review of room temperature and humidity logs revealed the laboratory did not document the room temperature and humidity for two out of two years (2020 - 2022). Record review of the package insert "Cliniqa Liquid Quality Control (QC) Immunoassay Control" revealed, "Cliniqa Liquid QC Immunoassay Control is stable until the expiration date on the vial label when stored unopened at less than or equal to - 20 degrees Celsius. Record review of temperature logs revealed the laboratory did not document the temperature of the freezer for two out of two years (2020 - 2022). On 3/8/22 at 12:35 p.m., the laboratory director was unaware the Individualized Quality Control Plan needed to be monitored and assessed and he did not know they needed to be documenting room temperature and humidity, and the freezer temperature as the Individualized Quality Control Plan stated.
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 record review and interviews the Laboratory Director failed to have an effective quality assurance program (See D6021), and failed to ensure employees had competency prior to patient testing (See D6029).
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and interview the Laboratory Director failed to have an effective quality assurance program for 2 out of 2 (2020-2022) years reviewed. The findings include: See D5791.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)

	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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review and interview the Laboratory Director failed to ensure Testing Personnel had competency evaluations prior to reporting patient results for one (#B) out of two Testing Personnel reviewed for two out of two years (2020 - 2022). The findings include: See D5209.