

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2168554	(X3) Date Survey Completed 06/29/2023
Name of Provider or Supplier Genesiscare Usa Of Florida Llc	Street Address, City, State 20601 E Dixie Hwy, Ste 330, Aventura, 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 recertification survey was conducted on June 27 - 29, 2023. Genesiscare USA of Florida LLC clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of the Laboratory Personnel Report, competency evaluations, and proficiency testing (PT) records, and interview, the laboratory failed to have all testing personnel rotate through performance of proficiency testing (PT) in the specialty of Hematology for three of four (2022 1st, 2nd, 3rd and 2023 1st) events. Findings Included: Review of the Laboratory Personnel Report, signed and dated by the Laboratory Director on 06/27/2023, listed three testing personnel (Testing Person A [TP-A], Testing Person B [TP-B] and Testing Person C [TP-C]). Review of the initial training records showed that TP-A's initial competency was dated 02/01/2021. Review of the initial training records showed that TP-B's initial competency was dated 09/14 /2021. Review of the initial training records showed that TP-C's initial competency was dated 11/01/2021. Review of the PT records from American Proficiency Institute showed the PT attestation forms were signed by TP-A as the "Person Performing Test" for the hematology PT for 2022 2nd, 3rd event, and 2023 1st event. On 06/29 /2023 at 9:52 AM, the Laboratory Consultant confirmed the lab had not rotated the performance of PT.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p>

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 review of the application submitted to change the Laboratory Director and the procedure manual, and interview, the laboratory failed to provide documentation that showed the Laboratory Director approved, signed, and dated the procedure manual from 01/07/2022 to 06/29/2023. Findings: Review of the laboratory's Clinical Laboratory Improvement Amendments (CLIA) Application for Certification submitted on 01/10/2022, noted the laboratory changed laboratory directors to the Current Laboratory Director effective on 01/07/2022. Review of the procedure manual showed the Previous Laboratory Director approved, signed and dated the procedure manual on 11/11/2020. On 06/29/2023 at 10:30 AM, the Laboratory Consultant stated she was unable to locate where the Current Laboratory Director had approved, signed and dated the procedure manual.

D5781

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on observation, review of package inserts and the temperature logs, and interview, the laboratory failed to document corrective actions for refrigerator temperatures that were not within the acceptable temperature range for 14 of 68 days from 10/25/2022 to 03/03/2023. Findings: During a tour of the laboratory on 06/27/2023 at 1:30 PM, the Sysmex XN-L Check reagent used for control and calibration verification were found in the laboratory's refrigerator. Review of the package insert for the Sysmex XN-L Check reagents showed the reagents needed to be stored at 2 - 8 degrees Celsius (C). Review of the laboratory's refrigerator temperature logs showed the temperature was out of range for the following dates: 10/25/2022 temperature 1.1 degrees C 11/07/2022 temperature 1.0 degrees C 11/08/2022 temperature 1.5 degrees C 12/08/2022 temperature 0.9 degrees C 12/12/2022 temperature 1.4 degrees C 12/16/2022 temperature 1.0 degrees C 12/22/2022 temperature 1.8 degrees C 01/03/2023 temperature 0.7 degrees C 01/04/2023 temperature 0.8 degrees C 01/10/2023 temperature 1.8 degrees C 01/17/2023 temperature 0.6 degrees C 01/23/2023 temperature 1.9 degrees C 01/25/2023 temperature 1.2 degrees C 02/03/2023 temperature 0.6 degrees C Review of the temperature logs for the refrigerator showed there was no corrective action documented. On 06/29/2023 at 9:48 AM, the Technical Consultant acknowledged there was no corrective action documented.

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of the test reports and interview, the laboratory failed to have the correct name and address of the laboratory for five of five patients, (#1, #2, #3, #4, #5). Findings: Review of the test reports for patient's #1 (dated 06/29/2023), #2 (dated 06/23/2023), #3 (dated 06/29/2023), #4 (dated 12/29/2022), and #5 (dated 11/17/2022), showed the name and address of the laboratory was incorrect. On 06/29/2023 at 11:17 AM, the Laboratory Consultant acknowledged the name and address of the laboratory needed to be corrected.

D6063

LABORATORY TESTING PERSONNEL

CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on review of the Laboratory Personnel Report and the personnel folders, and interview, the laboratory failed to verify the educational qualifications (degrees) for 1 (Testing Personnel - B [TP-B]) of 3 Testing Personnel (TP-A, TP-B, TP-C) (See D6065).

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on review of the Laboratory Personnel Report and the personnel folders, and

interview, the laboratory failed to verify the educational qualifications (degrees) for 1 (Testing Personnel - B [TP-B]) of 3 Testing Personnel (TP-A, TP-B, TP-C). Findings: Review of the Laboratory Personnel Report, signed by the Laboratory Director on 06/27/2023, showed there were three employees listed as moderate complexity testing personnel. Review of the laboratory personnel folders showed there was no documentation of the educational degree for TP-B available for review. On 06/29/2023 at 9:52 AM, Laboratory Consultant stated she could not find the educational degree for TP-B.