

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0999920	(X3) Date Survey Completed 04/15/2022
Name of Provider or Supplier Genesis Medical Laboratory	Street Address, City, State 6504 Nw 77 Ct, Miami, 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 4/14/2022 to 4/15/2022 at Genesis Medical laboratory. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to store chemistry and molecular reagents in freezers according to manufacturer guidelines. Findings included: During observation on 4/14/2022 at 11:20 AM in the chemistry room revealed freezer # 4 temperature listed as -18.3 Celsius (C). In the freezer #4 were the following reagents that required storage of -20 C to -70 C: 1. 6 out of 6 Biorad Therapeutic Drug monitoring control Level 1 2. 6 out of 6 Biorad Therapeutic Drug monitoring control Level 3 3. 4 out of 4 Immunoassay Plus Control level 1 4. 3 out of 3 Immunoassay Plus Control level 3 5. 1 out of 1 liquid assayed Multi level 3 Review of January 2022 -March 2022 Freezer #4 Temperature log revealed 45 out of 65 days from 1/3/2022 - 3/31/2022 freezer temperatures were recorded below -20 C. During observation on 4/14/2022 at 3:54 PM in the Molecular hallway revealed freezer # 1 temperature listed as -30 C. In the freezer 1 were the following reagents that required storage of -15 C to -25 C: 1.96-Well Spectral Calibration Plate ABY for multiplex qPCR 2.HDPCR SARS- CoV-2 Box1 HT Assay 3.HDPCR SARS- CoV-2</p>

Box 2 Controls 4.HDPCR SARS- CoV-2 Box 2 Calibrators During an interview on 4/15/2022 at 3:45 PM, the office manager and staff confirmed the laboratory failed to store chemistry and molecular reagents in freezers according to manufacture guidelines.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to complete interfering substances in their validation for their laboratory developed COVID Test HDPCR SARS-CoV 2 assay since 1/23/2021. Findings Included: A review of Genesis HDPCR SARS COV-2 validation revealed the laboratory developed the COVID Test HDPCR SARS-CoV 2 for testing for COVID. There was no written documentation that interfering substances had been performed in the validation. The validation had been signed by the laboratory director on 1/23/2022, 4/7/2021 and 7/29/2021. During an interview on 4/15/2022 at 3:00 PM, the office manager stated 79,050 PCR COVID-19 Test have been performed from 7/29/2021 to present. During an interview on 4/15/2022 at 3:44 PM, the molecular supervisor confirmed that interfering substances was not performed in the validation before patient testing.