Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0999920	11/19/2020
Name of Provider or Supplier	**Street Address, City, State**	
Genesis Medical Laboratory	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	An unannounced complaint survey (#2020017755) conducted on 11/18/2020 -11/19 /2020, found that Genesis Medical Laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following condition was cited: -D3000
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). This CONDITION is not met as evidenced by: Based on record review and staff interview the laboratory failed to follow the Florida Emergency Rule 64DER20-18 (64D-3.029) to report all COVID 19 tests results immediately to the Florida Department of Health (DOH) from 4/15/2020 to 11/19 /2020. See 3009
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to follow the State of Florida Emergency Rule 64DER20-18(64D-3.029) to report all positive and negative COVID-19 test results immediately to the Department of Health (DOH), failed to have a procedure in place to report real time polymerase chain reaction (RT-PCR)

	Coronavirus 2019 (COVID-19) and COVID-19 immunoglobulin G (IgG) results to the Florida Department of Health (FDOH) as per current guidelines, and the laboratory failed to ensure that the FDOH received all the notifications for the tests performed from 4/15/2020 to 11/19/2020. Findings include: -Review of policy GEN-14, for Reporting Results signed by the laboratory Director on 3/16/2020, stated that for Infection Disease Test positive (reactive) a result report must be faxed to FDOH using a report form, to keep record of the form and the fax confirmation (Hepatis B, C, RPR, Chlamydia, Gonorrhea). No further revision done after addition of the PCR COVID-19 added to the test menu on 4/15/2020 and COVID-19 IgG on 5/2020. -Review of FDOH Emergency Rule 64DER20-26 (64D-3.029) of April 10th 2020, revealed for COVID-19; the timeframe is immediately and had special reporting requirements. Results should be reported and accompanied by any testing conducted (positive and negative). For laboratories performing electronic laboratory reporting as described in subsection 64D-3.031 (5). F.A.C., all test results (positive and negative) are to be submitted, including screening test results (positive and negative). -The laboratory performed 42618 COVID-19 PCR test from 4/22/2020 to 11/10/2020 and 2435 IgG test from 5/2020 to 11/2020. -Review of Genesis report of test results for PCR COVID-19 on 7/1/2020 showed that the laboratory performed 187 tests, for 32 tests positive and 155 negatives. Review of the notifications sent to FDOH revealed the following: a) Fax confirmation records for PCR COVID-19 sent to FDOH for 7/1 /2020 showed 6 fax reports (each with 4 positive case reports): b) 3 fax confirmation with the following PCR COVID_19 cases: 373352, 373397, 373398,373278, 373618, 373631, 373485, 373541, 373658,372632, 373613 and 373614, had error in transmission. No documentation available of further transmission to the FDOH. c) 3 fax confirmation reported OK transmission for PCR COVID-19 cases: 373610, 373600, 373273, 373277, 373300, 373350, 373351, 373464, 373287, 373290, 373291, 393292). d) No documentation of report to the FDOH found for 8 PCR COVID-19 positive cases (373458, 375459, 373460, 373461, 373468, 373473, 373639 and 373644). e) No documentation of the report to the FDOH of the 155 PCR COVID-19 negative cases. -Review of the FDOH report records for serology COVID-19 IgG on 9/11/2020 revealed that the laboratory had 16 cases listed on 4 reporting forms, but no fax confirmation found of the notifications sent. During an interview on 11/19/2020 at 5:30 PM, the general supervisor, confirmed that the laboratory failed to have a policy that follow the guidelines for reporting COVID-19, that the laboratory failed to report negative cases for PCR COVID-19, that the laboratory failed to have all fax confirmation of the reports sent to the FDOH and failed to ensure that all PCR COVID-19 cases tested were reported to the FDOH.