Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0280554	10/06/2021
Name of Provider or Supplier	**Street Address, City, State**	
Finlay Clinical Laboratory Inc	330 Sw 27th Ave Ste 101, 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 conducted on 10/05/2021 to 10/06/2021 found the FINLAY CLINICAL LABORATORY INC not in compliance with 42 CFR Part 493, Requirements for Laboratories.
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). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to report 26,240 test results to Florida Department of Health (FDOH) from 03/09/2021 to 09/30/2021. The laboratory performed 24,837 nucleic acid amplification (NAAT) tests using Aptima Hologic test for the detection of severe acute respiratory syndrome coronavirus 2 (SARS-COV-2), 733 SARS-CoV-2 S1/S2 Immunoglobulin G (IgG) and 670 Immunoglobulin M (IgM) to SARS-COV-2 tests with Liaison DiaSorin test kit. Findings include: -Review of the FDOH notification records, revealed the laboratory was notified on 03/09/2021 that their reporting system was not communicating with the FDOH SARS-COV-2 reporting system and while their system entered in production phase, they will have to report daily by fax. -Review of the fax records sent to the FDOH revealed the laboratory failed to report 24,837 results for NAAT Aptima Hologic test for detection of SARS-COV-2, 733 SARS-CoV-2 S1/S2 IgG

	results and 670 IgM SARS-COV-2 results using Liaison DiaSorin tests from 03/09 /2021 to 09/30/2021. During an interview on 10/05/2021 at 2:00 PM, the Technical Supervisor (TS) explained that the laboratory had been working with the FDOH Electronic Reporting System (ELR) group since they received the notification and confirmed the laboratory failed to report the cases listed above for the period of reference because they understood they could do a back log report after the ELR system was set up.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on record review, and interview, the laboratory failed to follow Qiagen QuantiFERON- Tuberculosis (TB) Gold Plus (QFT-Plus) manufacturer's instructions to ensure the quality of blood specimens prior to testing by documenting the time and date of blood specimens received and incubated. Findings include: Review of QFT-Plus Instructions for Use stated "Tubes must be transferred to a 37 Celsius (C) 1C incubator within 2 hours. If QFT-Plus Blood Collection Tubes are not incubated at 37 C directly after blood collection and shaking, invert the tubes to mix 10 times (10x) prior to incubator at 37 C. Incubate the QFT-Plus Blood collection tubes upright at 371 C for 16 to 24 hours. In order to obtain valid results from the QFT-Plus assay, the operator needs to perform specific tasks within set times. Prior to harvesting plasma, samples in QFT-Plus Blood Collection Tubes must have been incubated at 37 C for 16-24 hours." QFT-Plus Blood Collection Tubes also contain the following controls: Nil (the negative control) and mitogen (the positive control). Review of QuantiFERON Incubator logs revealed the laboratory was not documenting the collection time and incubation in and out time for QFT blood specimens from 01/01 /2020 to 10/06/2021. During an interview on 10/06/2021 at 12:00 PM, the Technical Supervisor (TS) confirmed laboratory failed to follow manufacturer's instructions to ensure the quality of blood specimens prior to testing by documenting the time and date of specimen received and incubated.