Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0940832	01/25/2022
Name of Provider or Supplier	**Street Address, City, State**	
Vicente E Roger Md Pa Dba Miami Pediatrics	1069 Kane Concourse, Bay Harbor Islands, 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 01/25/2022 found that VICENTE E ROGER MD clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following condition was cited: -D3000. Facility Administration
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 records review and interview with Testing Personnel (TP) A, the laboratory failed to report 158 SARS-COV-2 Antigen test results to Florida Department of Health (FDOH) from 08/31/2021 to 12/30/2021. Findings include: -Review of Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS- 116) signed by the Laboratory Director on 01/10/2022, revealed that the laboratory performed Access Bio Care Start COVID-19 Antigen test to detect SARS CoV-2 Antigen. -Review of records revealed that the laboratory started testing with Care Start COVID-19 Antigen test on 08/31/2021. - Review of Electronic Laboratory Reporting Portal Record revealed that the laboratory started using the Electronic Reporting System (ELR) on 01/20/2022. -Review of reporting records revealed that

	the laboratory failed to report 158 Antigen test results. During an interview on 01/25 /2022 at 11:30 AM, TP A confirmed that the laboratory failed to report 158 test results to FDOH from 08/31/2021 to 12/30/2021.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to stop using whole blood Hematology Controls (HC WBC) for HEMOCUE WHITE BLOOD CELLS (WBC) test after the new expiration date (01/05/2022) from 01/05/2022 to 01/25 /2022. Findings include: -Review of R&D Systems HC WBC controls instructions for use in the section "STABILITY AND STORAGE" required storage at 2 - 8 degrees Celsius and stated "Opened vials are stable for 30 days provided they are handled properly." -During the laboratory tour on 01/25/2022 at 09:30 AM, the surveyor observed that the laboratory had in use 3 HC WBC controls with an open date 12/06 /2021 but no new expiration date registered. Photographic evidence collected. -As per package instruction the controls expired on 01/05/2022. The laboratory tested 1 patient on 01/19/2022. During an interview on 01/25/2022 at 11:30 AM, Testing Personnel A, confirmed that controls in use were not labeled with the new expiration date and that the laboratory tested 1 patient with expired controls.