Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0929531	03/24/2021
Name of Provider or Supplier	**Street Address, City, State**	
Boca Raton Physicians Pa	1905 Clint Moore Rd Ste 201, Boca Raton, 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 03/24/2021 found that the BOCA RATON PHYSICIANS PA clinical 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). (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 44 out of 44 negative results for the Cobas SARS-Cov-2 & influenza A/B test from 12/28/2021 to 03/24/2021. Findings include: -Review of patient reports for the Cobas SARS-Cov-2 & Influenza A/B nucleic acid test revealed that the laboratory tested 53 patients from 12/28/2021 to 3/24/2021. -Review of reports to the Department Of Health (DOH) revealed the laboratory failed to report the 44 negative cases. During an interview on 03/24/2021 at 2:00 pm, the office manager confirmed the laboratory failed to report the 44 negative cases for Cobas SARS-Cov-2 & influenza A/B from 12/28/2021 to 03 /24/2021 to the DOH.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)

	Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform quality control lot to lot comparisons from 5/24/2019 to 3/24/2021 for hematology and chemistry controls. Findings include: -Review of the Quality Control policy on page QC7 on section J, revealed that the laboratory had to run a new control lot to establish a new mean and verify the values on the manufacturer range report before use for patient testing. -Review of quality control records from 5/13/2019 to 3/24/2021 for Abbot Cell Dyn 1700 (Hematology), Roche Integra 400 Plus (Chemistry) and Roche Cobas e411 (Chemistry), revealed the laboratory failed to perform the lot to lot verification for new control lots. During an interview on 3/24/2021 at 2:30 pm, the TP # A confirmed the laboratory failed to perform lot to lot quality control verification for the period referenced.