Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0907702	10/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
David B Hevert Md Pa	3848 Fau Blvd Ste 210, 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	An announced CLIA recertification survey was conducted at David B. Hevert MD on 10/20/2021. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
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 SARS-CoV-2 antibody results to the Department of Health since August 31, 2021 for a total of 282 Patient results. Findings Included: Review of the CMS 116 revealed that the laboratory performed Anti-SARS-CoV-2 and SARS-CoV-2-Spike-AB antibody testing on their Roche Cobas E411 Chemistry analyzer. Review of policy and procedures (signed by the Laboratory Director on 04/19/2021) revealed a print off from the Department of Health stating that "COVID-19 antibody test results are no longer required to be reported to the Florida Department of Health (Department)." Interview on 10/20/2021 at 4:00 PM Testing Person #A and #B confirmed that they stopped reporting their SARS-CoV-2 antibody results to the Department of Health since August 31, 2021 and that they have tested 282 Patient samples since they stopped reporting.

D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to evaluate American Proficiency Institute (API) proficiency results that received a score of "Not Graded" for 3 (1st and 2nd event in 2020 and 2nd event in 2021) out of 6 (1st, 2nd, and 3rd events in 2020 and 2021) Testing Events (TE) in Chemistry and 1 (3rd event in 2020) out of 6 (1st, 2nd, and 3rd events in 2020 and 2021) TE in Hematology. Findings Included: Review of API proficiency testing results for Chemistry revealed a score of "Not Graded" for Folate specimen IA-01 in the 1st TE of 2020, IA-07 in the 2nd TE of 2020, and IA-07 in the 2nd TE of 2021. Review of API proficiency testing results for Hematology revealed a score of "Not Graded" for Urine Sediment specimen US-06 in the 3rd TE of 2020. There was no evaluation or corrective action for the aforementioned analytes. Interview on 10/20/2021 at 12:00 PM Testing Person #A and #B confirmed that the "Not Graded" analytes had not been evaluated.