Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 49D1052366	**(X3) Date Survey Completed** 09/12/2022
Name of Provider or Supplier Pediatric Partners Of Stafford, Pc	**Street Address, City, State** 110 Soaring Eagle Drive, Stafford, VA	
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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was conducted at Pediatric Partners of Stafford, PC on September 8, 2022 by a Medical Facilities Inspector from the Virginia Department of Health, Office of Licensure and Certification. The surveyor performed a focused COVID-19 Reporting Survey which concluded on September 12, 2022. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. During the recertification survey, the inspector found that the laboratory was not in compliance with the following Condition under 42 CFR part 493 CLIA Regulation: D3000- 42 CFR. 493.1100 Condition Facility Administration (Reporting of SARS-CoV-2 test results).
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 a laboratory tour, manufacturer's instruction for use (IFU), SARS CoV-2 patient test records, lack of documentation and interviews, the laboratory failed to report positive SARS-CoV-2 Antigen test results as required for two hundred forty-two (242) patients on one-hundred ten (110) of 110 testing dates reviewed (timeframe April 4, 2022 to September 8, 2022). Findings include: 1. During a tour of the laboratory on September 8, 2022 at approximately 9:00 AM, the inspector noted the

	laboratory performs SARS CoV-2 Antigen testing using the Quidel QuickVue SARS Antigen Test. 2. Review of the package insert for the Quidel QuickVue SARS Antigen Test revealed the following statement, "Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate." 3. Review of the laboratory's SARS CoV-2 patient test records revealed 242 patients with positive SARS CoV-2 Antigen tests were performed and resulted on 110 testing days from April 4, 2022 to September 8, 2022. The inspector requested to review documentation of the reporting of the positive SARS CoV-2 Antigen test results to the Virginia Department of Health. The laboratory provided no documentation for review. In an interview with the nurse manager and testing personnel on September 8, 2022 at approximately 12:00 PM, the nurse manager stated, "I didn't realize we were required to report positive SARS CoV-2 Antigen test results to the Virginia Department of Health." 4. 242 positive SARS CoV-2 Antigen test results were not reported as required during the timeframe of review (110 testing dates). The laboratory performed nine-hundred fifty-nine (959) SARS-CoV-2 Antigen tests during the timeframe of review. 5. In an exit interview with the nurse manger on September 12, 2022 at approximately 11:15 AM, the above findings were confirmed.