Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0227781	12/05/2022
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Center-West End	2304 John Rolfe Parkway, Richmond, 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 CLIA recertification survey was conducted at Pediatric Center-West End on November 29, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The survey included a follow up interview with the Operations Manager and Lead Laboratory Tech/Floor Nurse on 12/01/22 and 12/05 /22 respectively. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific mandatory Condition deficiency cited as the following 42 CFR part 493 CLIA Regulation: D1002- 42 CFR. 493.41 Reporting of SARS-CoV-2 Test Results.
D1002	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 tour, review of procedures, test log records, electronic medical record (EMR) log, lack of documentation, and interviews, the laboratory failed to report seven hundred three (703) positive patient SARS-CoV-2 (COVID-19) results assayed on one hundred thirty-three (133) days during five of eleven months reviewed in calendar year 2022. Findings include: 1. During a tour of the laboratory on 11/29/22 at approximately 10:00 AM the inspector noted a BD Veritor Plus analyzer in use for COVID-19 testing and requested to review the procedure, test logs, and evidence of results reporting to state agency. 2. Review of the laboratory procedures revealed a BD Veritor SARS-CoV-2 procedure which included the manufacturer's package insert / instructions for use (IFU). The IFU outlined General Instructions as: "Laboratories within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities." 3. Review of available test log

	records revealed there was no evidence of reporting COVID-19 results to the state agency during the timeframe of June 1, 2022 to the date of the inspection, 11/29/22. The inspector requested evidence of reporting for the five month timeframe outlined above. The Lead Laboratory/Floor Nurse stated on 11/29/22 at approximately 11:30 AM, "We were registered online to report to the department of health but for some reason the staff have not been reporting since June." 4. Review of the electronic medical record (EMR) Allscripts test logs revealed 703 positive COVID-19 tests were resulted on the following number of days while not being reported to the state agency: June 2022: twenty-three (23) days, July 2022: twenty-one (21) days, August 2022: twenty-four (24) days, September 2022: twenty-two (22) days, October 2022: 22 days, November 2022: 21 days. A total of 133 days from June 1, 2022 to 11/29/22 during which 703 positive COVID-19 tests were resulted by the laboratory while not reported to the state agency per procedure protocol. 5. An exit interview with the Lead Laboratory/Floor Nurse on 11/29/22 at approximately 12:00 PM, follow up interviews with the Operations Manager on 12/02/22 at 3:00 PM, and Lead Laboratory/Floor Nurse on 12/05/22 at 5:00 PM confirmed the above findings.