Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0221934	11/05/2020
Name of Provider or Supplier	**Street Address, City, State**	
Virginia Pediatric Group	8316 Arlington Blvd #300, Fairfax, 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 on-site CLIA recertification survey was conducted at Virginia Pediatric Group on November 5, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview on 09/29/2020 and virtual record review conducted on 10/29/2020. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiency is as follows: .
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual, a review of the Food and Drug Administration's (FDA) Emergency Use Authorization (EUA) website, review of available patient and quality control (QC) logs, and lack of documentation and interviews, the laboratory failed to document performance of negative and positive external quality control (QC) materials for one (1) non FDA approved COVID-19 IgG/IgM test methods while reporting eighty-four (84) patient COVID-19 antibody results from June 22, 2020 until October 28, 2020. Findings include: 1. In a video conference interview with the primary testing personnel on October 29, 2020 at approximately 9:30 AM, it was revealed that the laboratory had been utilizing a COVID-19 Antibody test kit labeled as "COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) manufactured by Zhejiang Orient Gene Biotech CO, Ltd during the timeframe of June 22, 2020 until October 28, 2020. 2. Review of the FDA website's published listing of COVID-19 EUA's granted for SARS CoV-2 antibody testing as of November 5, 2020 revealed no EUA granted for

	the "COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) manufactured Zhejiang Orient Gene Biotech CO, Ltd. 3. During the video conference with the primary testing personnel on October 29, 2020 at approximately 9:30 AM, the inspector asked for a description of the laboratory's QC protocols and patient test logs for the test methods outlined above. The primary testing personnel stated "We use the internal built in QC. We did not use external quality control materials." 4. Review of available patient and QC logs revealed that the facility reported 84 COVID-19 IgG/IgM results while performing zero (0) negative or positive external controls for each day of patient testing from June 22, 2020 until October 28, 2020. The inspector requested documentation of the performance of a negative and positive controls each day of patient testing from June 22, 2020 and October 28, 2020. The laboratory provided no documentation of the performance of controls. 5. An interview with the primary testing personnel on November 5, 2020 at approximately 10:15 AM, the findings were confirmed.