Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0227389	01/30/2023
Name of Provider or Supplier	**Street Address, City, State**	
Richmond Pediatric Associates	9900 Independence Park Drive - Suite 100, 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 the Richmond Pediatric Associates on 01/30/23 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows: The laboratory is performing COVID-19 testing and is in compliance with the applicable COVID-19 reporting requirements.
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on the review of the CASPER 0096D CLIA Application and Survey Summary Report, proficiency testing (PT) records and an interview, the laboratory failed to participate in one of four Complete Blood Count (CBC) events reviewed. Record review included third PT event in 2021 and three PT events in 2022. Findings include: 1. Review of the CASPER 0096D CLIA Application and Survey Summary Report and the College of American Pathologists (CAP) PT records for the third event in 2021 and three events in 2022 revealed the laboratory received a score of 0% for the following event: 2022 Event 1 FH A - 0%- for the CBC module (Notation by CAP-

	failure to receive results). 2. An exit interview with the testing personnel on 01/30/23 at 1510 confirmed the findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a tour of the laboratory, review of policy and procedures (P&P), quality control (QC) records, lack of documentation, patient test data and interview, the lab failed to follow the established P&P of performing external QC materials with every new shipment and new lot number of assay kits for two of 15 lot numbers received from 06/01/21 up to the date of survey on 01/30/23, reporting 110 patients. Findings include: 1. A tour of the lab on 01/30/23 at approximately 1215 revealed the lab utilized the Quidel Solana instrument to perform the Solana GAS assay for the detection of Group A beta-hemolytic Streptococcus. 2. Review of the P&P revealed an Individualized Quality Control Plan (IQCP), approved by the lab director on 11/16 /18, that defined performing external QC materials every new shipment and new lot number of assay kits for the abovementioned analyte. 3. Review of QC records and patient test data from 06/01/21 up to the date of survey on 01/30/23 revealed lack of documentation of external QC materials for the following of assay kits: Lot number 183020 (expiration date 08/07/22) utilized from 07/22/21 to 09/24/21 and reporting 65 patients; Lot number 191098 (expiration date 01/08/23) utilized from 09/25/21 to 10 /27/21 and reporting 45 patient. 4. An exit interview with the testing personnel on 01 /30/23 at approximately 1520 confirmed the findings.