Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0227708	07/18/2023
Name of Provider or Supplier	**Street Address, City, State**	
Monument Avenue Pediatrics Pc	3602 Monument Ave, 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 Monument Avenue Pediatrics, PC on July 18, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited is as follows:
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: A. Based on review of procedures, hematology proficiency testing (PT) records, lack of documentation, and an interview, the laboratory failed to follow their PT policy for result retention/review for one (1) of five (5) PT events reviewed on the day of the inspection, July 18, 2023. Findings include: 1. Review of the laboratory's procedures revealed a Proficiency Testing protocol that stated, "all results will be printed, reviewed, and signed by the lab director and placed in the PT binder." 2. During a review of the American Association of Bioanalysts (AAB) PT results (2021 Event 3, 2022 Events 1-3, 2023 Event 1), the inspector noted no results were retained in the PT records for AAB Hematology 2022 Event 2. The inspector requested to review the results for the event outlined above. The lead nurse logged into the AAB portal and provided results for the inspector to review via screen shot. The nurse coordinator stated on 7/18/23 at approximately 3:30 PM, "I am not sure why the results are not in our PT binder." The inspector requested to review documentation that the results had been reviewed. The nurse coordinator stated at approximately 3:40 PM, "I do not have the copy where our medical director signed to show you today. They might still be in the director's office." 3. An interview with the nurse coordinator on 7/18/23 at

	approximately 4:00 PM confirmed the above findings. B. Based on review of procedures, quality assurance (QA) protocols, analyzer maintenance records, lack of documentation, and an interview, the laboratory failed to follow their lab director (LD) approved procedure to document performance of hematology analyzer maintenance protocols during twenty-three (23) months reviewed (September 2021 to the date of the survey on July 18, 2023). Findings include: 1. Review of the laboratory's procedures revealed the following protocol: MindRay BC 3200 hematology protocol for scheduled maintenance instructions: Daily Start Up: Perform start up and verify auto background passes, perform quality control checks; Daily Shut Down: General cleaning to include the sample tube holder with alcohol swab for blood and debris, empty waste reservoir, check reagent levels; Weekly: Zap Aperture procedure, Flush Apertures, Probe Cleanser Cleaning; As Needed: EZ Cleanser Cleaning, Clean Baths, Replace Air Filter. 2. The laboratory's QA protocols included the 2021 Centers for Medicare and Medicaid Services Statement of Deficiencies Plan of Correction (CMS-2567 POC, LD signed/approved 9/1/21). Review of the CMS-2567 POC revealed an outlined LD approved corrective action plan that stated "Documentation of all MindRay scheduled maintenance will be documented when performed. This will included flush apertures, probe cleaning, EZ cleanser cleaning, cleaning baths, filter replacement, and weekly at the time of probe cleaning the the sample tube platform will be cleaned." 3. Review of the laboratory's hematology log book revealed field service reports but no documentation of the instrument's scheduled maintenance outlined above for the timeframe of September 2021 to 7/19 /23. The inspector requested to review the logs of the required maintenance. No records were available for review. 4. An interview with the nurse coordinator on 7/18 /23 at approximately 4:00 PM confirmed the above findings.