Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0227708	08/18/2021
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 August 18, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The inspector noted that the laboratory performs SARS-CoV-2 (COVID-19) testing and was in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services CLIA Application and Survey Summary (CMS CASPER 96D), proficiency testing (PT) records, and an interview, the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for Hematocrit (HCT) in one (1) out of six (6) Hematology testing events reviewed. Findings include: 1. On 08/08/21, prior to the on-site survey, the inspector's review of the laboratory's CMS CASPER 96D report revealed the laboratory received a 40 % score for HCT in the first event of calendar year 2021. 2. During the onsite survey on 08/18/21, the inspector reviewed 6 American Proficiency Institute (API) hematology PT records (2019 Events 2-3, 2020 Events 1-3, 2021 Event 1). The review revealed the following failed HCT challenge scores on the 2021 1st Event: HEM-02 resulted as 14, acceptable range 15-18; HEM-03 resulted as 49, acceptable range 50-57, HEM-04 resulted as 24, acceptable range 25-30; resulting in unsatisfactory analyte performance for the testing event. 2. An exit interview with the nurse coordinator at approximately 11:15 AM confirmed the above findings
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE

	CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, lack of documentation, and an interview, the laboratory failed to document evaluation of unsatisfactory scores for three (3) of five (5) Hematocrit (HCT) and one (1) of 5 Platelet (PLT) challenges reported on the 2021 Hematology Event 1 report. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) PT records (2019 Events 2-3, 2020 Events 1-3, 2021 Event 1) revealed no evidence of evaluation for each of the following failed analyte scores: 2021 API Event 1: HCT (HEM-02, HEM-03, HEM-04), PLT (HEM-02). The inspector requested to review documentation that the laboratory evaluated the 4 unacceptable challenge results outlined above. Documentation was not available for review. 2. An exit interview with the nurse coordinator at approximately 11:15 AM confirmed the above findings
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on a laboratory tour, review of procedures, and interviews, the laboratory failed to follow their policy for specimen labeling for two (2) of 2 collected COVID-19 Polymerase Chain Reaction molecular (PCR) patient specimens observed in the reference laboratory send out box on August 18, 2021 at 9:15 AM. Findings: 1. During a laboratory tour with the nurse coordinator at approximately 9:15 AM on 08 /18/21, the inspector noted 2 patient specimen swabs in transport media tubes with requisitions for COVID-19 PCR (dated 8/18/21) packaged in clear plastic bags and racked in a box labeled as reference lab send out testing. The inspector noted/inquired regarding the observation that neither of the 2 collected specimen tubes were labeled. The nurse coordinator stated" "our electronic medical record zebra printer is malfunctioning today and the staff plans to label the tubes once it is repaired. I will have someone label the tubes as soon as possible." 2. Review of the laboratory procedure manual revealed a policy which defined specimen identification/labeling criteria that stated: "Label all specimens with two identifiers using a sharpie pen once collected, before leaving the exam room". 3. An exit interview with the nurse coordinator at approximately 11:15 AM confirmed the above findings
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for

	specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a tour, review of procedures, manufacturer's operation guide, and an interview, the laboratory failed to include a written policy or a protocol for patient Complete Blood Count (CBC) critical value results assayed on the MindRay 3200 hematology analyzer during the twenty-eight (28) months reviewed (April 2019 to the date of the survey on August 18, 2021). Findings include: 1. During a tour of the laboratory at approximately 9:30 AM, the inspector noted one (1) MindRay 3200 hematology analyzer (Serial Number 85100069) in use for patient CBC testing. The inspector noted no critical alert ranges were posted in the laboratory. 2. Review of the laboratory's procedure manual revealed no written critical value policy or protocol for CBC critical (panic) value results assayed on the MindRay hematology analyzer. The inspector inquired how CBC results are placed into patient records and if established critical values were available for review. No panic value/critical range for the laboratory's MindRay CBC assay was available for review. The nurse coordinator stated on 8/18/21 at approximately 10:00 AM: "We enter the CBC panel results into our electronic medical record manually. We do not have critical values posted or in our procedure book yet. I do not think we have critical values formally established but the staff would take abnormal results to the physician immediately." 3. Review of the MindRay BC-3200 Operation Manual revealed start up instructions that included the statement: "establish your laboratory's panic values". 4. An exit interview with the nurse coordinator at approximately 11:15 AM confirmed the above findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a tour, review of manufacturer's operations manual, instrument maintenance logs, interviews, and lack of documentation, the laboratory failed to document performance of hematology analyzer maintenance protocols during twenty-eight (28) of 28 months reviewed (April 2019 to the date of the survey on August 18, 2021). Findings include: 1. During a tour of the laboratory at approximately 9:30 AM, the inspector noted a hand written posted note attached to the MindRay 3200 hematology

	analyzer that indicated "probe cleaning done 8/13/21". The inspector noted that the MindRay sample tube platform was dirty with brown stains/ dried particles. The inspector observed no maintenance log in the area of the bench top hematology testing. 2. Review of the MindRay BC 3200 operations manual revealed manufacturer's 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. 3. Review of the laboratory's hematology maintenance log books revealed field service reports but no documentation of the instrument's scheduled maintenance outlined above. The inspector inquired of the laboratory's policy related to the frequency of the maintenance. The nurse coordinator stated on 8 /18/21 at approximately 10:30 AM: "We do the daily maintenance and the weekly probe clean but we do not have a log to record when we do it. We do put a sticky note on the instrument each Friday so that the staff knows that it was done. Our lab director also assists to verify that someone puts the note up each week that probe clean is done." 4. An exit interview with the nurse coordinator at approximately 11:15 AM confirmed the above findings.