Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0227781	11/29/2022
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 laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows and includes a Condition under 42 CFR part 493 CLIA Regulation: D5400 -42 CFR. 493.1250 Analytic Systems.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a tour, review of manufacturer's instructions for use (IFU), procedures, user guide/package inserts, test logs, daily temperature/environment logs, manufacturer's operations manual, hematology analyzer maintenance records, instrument calibrations, lack of documentation, and interviews, the laboratory failed to: 1. have a written policy on protocols to report patient SARS-CoV-2 (COVID-19) positive results to the state agency during the timeframe of June 1, 2022 to the date of the inspection on November 29, 2022. See D5401; 2. monitor refrigerator temperatures to ensure manufacturer's storage requirements were followed for hematology quality control materials utilized for Complete Blood Count (CBC) patient testing for three of twelve months reviewed in calendar year 2021. See D5413; 3. document performance of required twice annual hematology instrument preventative maintenance in calendar year 2021. See D5429; 4. perform CBC calibration procedures for patient testing on

	the Abbott Emerald analyzer every six months according to their procedure in calendar year 2021. See D5437.
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: Based on a tour, review of manufacturer's instructions for use (IFU), procedures, test logs, lack of documentation, and interviews, the laboratory failed to have a written policy on protocols to report patient SARS-CoV-2 (COVID-19) positive results to the state agency during the timeframe of June 1, 2022 to the date of the inspection on November 29, 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. 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 SARS-CoV-2 results to the appropriate public health authorities." 3. Review of the policies and procedures revealed no documentation of a policy for reporting patient COVID-19 results to the state agency. The inspector inquired of the reporting protocols to ensure positive patient results were reported to the Virginia Department of Health (VDH). No policy was available for review. The Lead Laboratory/Floor Nurse stated at approximately 11:30 AM on 11/29/22: "Our staff were enrolled and reporting online to VDH but at first of June this year, they discontinued logging in to report and we do not have a written policy yet." 4. Review of test logs revealed 1,165 positive COVID-19 tests were resulted during the five month timeframe outlined above (6/1/22-11/29/22). 5. An exit interview with the Lead Laboratory/Floor Nurse on 11/29/22 at approximately 12:00 PM confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a tour, review of procedures, manufacturer's user guide/package inserts, daily temperature/environment logs, lack of documentation, and an interview, the laboratory failed to monitor refrigerator temperatures to ensure manufacturer's storage requirements were followed for hematology quality control (QC) materials utilized for Complete Blood Count (CBC) patient testing for three of twelve months reviewed in

	calendar year 2021. Findings include: 1. During a tour of the laboratory on 11/29/22 at approximately 10:00 AM, the inspector noted Abbott Cell-Dyn QC vials stored in refrigerator labeled #1. The refrigerator was monitored with a digital Fridge-Tag 2L thermometer. The inspector inquired regarding the laboratory's protocol for recording refrigerator temperatures. The Lead Laboratory/Floor Nurse responded at approximately 10:15 AM, "The staff write the temperature reading from the thermometer onto a log each day and we also print out the digital report monthly." 2. Review of the laboratory's procedures revealed Quality Assurance protocols that outlined daily monitoring of environmental conditions that included laboratory refrigerator temperatures. The policy stated, "Monitor temperatures closely, staff is to write initials and record temperatures daily and after each month has ended the logs will be retained for three years" 3. Review of the Abbott manufacturer's guidelines revealed the following requirements: Cell-Dyn QC package insert - "Stable through expiration date when stored 2-8 C, opened stability is eight consecutive days after open stored at 2-8 C". 4. Review of the available refrigerator temperature monitoring records for calendar year 2021 revealed no records for the following three months: January, February, March. The inspector requested to review documentation of the refrigerator monitoring to manufacturer's specifications. No written temperature logs or digital Fridge-Tag 2L data log records for the three months outlined above were available for review. 5. An exit interview with the Lead Laboratory/Floor Nurse on 11 /29/22 at approximately 12:00 PM 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 review of manufacturer's operations manual, hematology analyzer maintenance records, lack of documentation, and an interview, the laboratory failed to document performance of required twice annual Abbott Emerald hematology instrument preventative maintenance in calendar year 2021. Findings include: 1. Review of the laboratory's hematology procedures revealed an Abbott Emerald Operations Manual with manufacturer's instructions to "perform Lubricating Syringe Pistons maintenance procedure twice annually" (under heading: Preventative Maintenance: Semi-Annual). 2. Review of the laboratory's available Emerald analyzer's maintenance logs revealed syringe pistons maintenance was documented once in the twelve months of calendar year 2021 (dated 6/8/21). 3. The inspector requested to review documentation of additional semi annual maintenance for the Abbott Emerald analyzer in calendar year 2021. No additional record was available for review. 4. An exit interview with the Lead Laboratory/Floor Nurse on 11/29/22 at approximately 12:00 PM confirmed the above findings.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2)

	Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of procedures, instrument calibration records, lack of documentation, and an interview, the laboratory failed to perform Complete Blood Count (CBC) calibration procedures for patient testing on the Abbott Emerald analyzer every six months, according to their procedure, during calendar year 2021. Findings include: 1. Review of the laboratory's procedure manual revealed a Hematology Calibration policy that outlined to calibrate CBC testing at a frequency of every six months. The policy stated: "Calibration is a procedure that confirms the accuracy and precision of the Emerald equipment and is performed every six months or more frequently as needed." 2. Review of the laboratory's 2021 Abbott Emerald instrument calibration documentation revealed one calibration record dated 06/08/21. 3. The inspector requested to review additional calibration records for the Abbott Emerald analyzer in calendar year 2021. No additional calibration documentation was available for review. 4. An exit interview with the Lead Laboratory/Floor Nurse on 11/29/22 at approximately 12:00 PM confirmed the above findings.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, and an interview, the laboratory failed to provide documentation that the technical consultant (TC) performed annual Hematology competency evaluations for three of six testing personnel (TP) in calendar year 2021. Findings include: 1. Review of the CMS 209 form revealed that the laboratory director (LD) also performed the duties of TC and that six testing personnel were identified as responsible for moderate complexity hematology Complete Blood Count patient testing in the twenty-three months reviewed (January 2021 through 11/29/22). 2. Review of personnel files revealed no annual hematology competency evaluations for TP A, B, and C during calendar year 2021. The inspector requested the records. No documentation was available. (SEE PERSONNEL CODE SHEET.) 3. An exit interview with the Lead Laboratory/Floor Nurse on 11/29/22 at approximately 12:00 PM confirmed the above findings.