Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0719539	11/01/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Center - Laburnum	4786 Finlay St, 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-Laburnum on November 1, 2018 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:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records, the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), and an interview, the laboratory failed to rotate PT among all personnel performing complete blood count (CBC) testing in calendar years 2017 and 2018. Findings include: 1. Review of the laboratory's CMS 209 form revealed five (5) testing personnel (TP) who perform patient CBC testing. (See Personnel Code Sheet.) 2. Review of the laboratory's 2016 (third event), 2017 (first, second, third events) and 2018 (first, second, third events) College of American Pathologists (CAP) hematology PT documentation (a total of 7 events) revealed that testing personnel B signed attestations of performing seven (7) of 7 events reviewed. 3. In an interview with the laboratory's primary testing personnel and clinical coordinator at approximately 2:30 PM , it was confirmed that the laboratory failed to rotate hematology PT among all personnel responsible for performing patient CBC testing in calendar years 2017 and 2018.
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 and policies, hematology calibration records, instrument user manual, and an interview, the laboratory failed to document calibration procedures every six (6) months for complete blood count (CBC) patient testing according to their policy and the hematology manufacturer's recommendation from August 22, 2017 to May 1, 2018. Findings include: 1. Review of the laboratory's procedure manual revealed a maintenance policy that outlined to calibrate CBC testing at a frequency of every six (6) months. 2. Review of the laboratory's hematology instrument calibration documentation from November 2016 to the date of the inspection on 11/1/18, a total of twenty-four (24) months, revealed the following three (3) month lapse in CBC calibration: The inspector noted documentation of calibration procedures on 8/22/17. The laboratory documented the next hematology calibration on 5/1/18. The inspector requested to review additional calibration records during the timeframe of February 2018 through April 2018. No additional calibration documentation was available for review. 3. Review of the Medonic M Series instrument user manual revealed maintenance logs and instructions that stated "calibration requirement is every six months". 4. In an interview with the primary testing personnel and clinical coordinator at approximately 2:30 PM, it was confirmed that the laboratory failed to document calibration procedures every 6 months for CBC testing according to their maintenance policy and Medonic M Series recommendation as outlined above.
D6055	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 whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), a tour, review of analyzer installation validation records, manufacturer's users guide, laboratory personnel files, and an interview, the technical consultant (TC) failed to document training and competency evaluations for three (3) of five (5) testing personnel after a hematology instrument change occurred in the laboratory on May 17, 2017. Findings include: 1. Review of the CMS 209 form revealed that the laboratory director (LD) also performs the duties of technical consultant (TC) and that there are five (5) testing personnel (TP) performing patient

	hematology testing. (Personnel Code Sheet attached.) 2. During a laboratory tour, at approximately 11:00 AM, the inspector noted the laboratory utilizing a Medonic M Series hematology analyzer for complete blood count (CBC) testing. The clinical coordinator stated: "we replaced our Abbott Cell Dyn 1800 with the Medonic in 2017". 3. Review of the laboratory's instrument validation records revealed a new hematology analyzer installation (M Series Serial Number 28800) performed by a Medonic field service technical specialist on 5/17/17. 4. Review of the Medonic M Series User's Guide revealed manufacturer's instructions that the "M Series Training Checklist is to be completed prior to patient testing for all operators". 5. Review of the laboratory personnel files and installation records revealed that the Medonic field service specialist completed onsite training checklists for TP A and TP B on 5/17/17. The inspector requested to review the training competency checklists and evaluations for TP C, TP D, and TP E. No documentation was available for review. 6. In an interview with the primary testing personnel and clinical coordinator at approximately 2:30 PM, it was confirmed that the TC failed to document the Medonic M Series hematology training competency evaluations for 3 of 5 testing personnel prior to utilizing the new instrumentation for patient testing from May 2017 through the date of the survey on November 1, 2018.