Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0719539	12/08/2022
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 the Pediatric Center-Laburnum on 12/08/22 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 are as follows: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D6063 - 42 C.F. R. 493-1421 Condition: Laboratory Testing Personnel. The laboratory is performing COVID-19 testing and is in compliance with the applicable COVID-19 reporting requirements.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on the review of proficiency testing (PT) records, lack of documentation, and an interview, the laboratory director failed to document an evaluation and corrective actions for the College of American Pathologists (CAP) Hematocrit (HCT) score of sixty percent (60%) received for the third event in 2022. Record review included all three events in 2022. Findings include: 1. Review of the CAP PT third event in 2022 records revealed the laboratory received a score of 60% for the HCT parameter. The records lacked documentation of an evaluation and corrective actions by the laboratory director or staff for the unsatisfactory score. 2. An exit interview with testing personnel A on 12/08/22 at approximately 11:25 AM confirmed the findings.

D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, lack of documentation, hematology maintenance records, daily quality control records, and interview, the laboratory director failed to ensure that one of two new TP had documented training and competency assessments prior to performing patient testing procedures for hematology on 12/09/21. Findings include: 1. Review of CLIA CMS-209 form revealed TP C listed as performing patient testing. (See attached TP Code Sheet.) 2. Review of TP records, and an interview with TP A on 12/08/22 at approximately 9:45 AM revealed that TP C was hired sometime in October 2021 and that there was no documentation of training and competency assessment prior to performing patient testing on 12/09/21. The inspector requested to review training and competency assessments performed for TP C. The documentation was not available for review. 3. Review of the hematology maintenance and daily quality control records revealed TP C performed daily procedures from 12/09/21 up to 02/08/22. 4. An exit interview with TP A on 12/08/22 at approximately 11:25 AM confirmed the findings.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the Center for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), available testing personnel records, lack of documentation, and interview with testing personnel (TP) A, the laboratory failed to provide documentation of education qualifications for two of two laboratory TP performing non-waived testing on the Medonic hematology analyzer at the date of survey on 12/08/22. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology

	from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the Center for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), available testing personnel records, lack of documentation, hematology maintenance records and daily quality control records, and interview with testing personnel (TP) A, the laboratory failed to provide documentation of education qualifications for two of two laboratory TP performing non-waived testing on the Medonic hematology analyzer at the date of survey on 12/08 /22. Findings include: 1. Review of the CLIA CMS 209 form and interview with TP A on 12/08/22 at 09:45 AM revealed two new TP. (See attached TP code sheet.) 2. Review of the available TP records revealed lack of documentation of the highest level of education for TP B and C. The inspector requested to review documentation of education for TP B and C. The documents were not available for review. 3. The training and competency records for TP B revealed documentation of training for the Medonic hematology analyzer assaying complete blood counts (CBC) on 11/22/21. TP B also signed the attestation statement for proficiency testing event B 2022. Review of the Medonic hematology analyzer maintenance sheets and daily quality control logs revealed TP C performed daily hematology procedures from 12/09/21 up to 02/08/22. 4. An exit interview with TP A on 12/08/22 at approximately 11:25 AM confirmed the findings.