

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0227389	(X3) Date Survey Completed 01/10/2025
Name of Provider or Supplier Richmond Pediatric Associates	Street Address, City, State 9900 Independence Park Drive - Suite 100, 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 Richmond Pediatric Associates on January 10, 2025 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 as follows.
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory's Hematology quality control reports, instrument performance verification records, and interviews, the laboratory director (LD) failed to document an evaluation/verification of the start-up studies of the Medonic Hematology analyzer prior to patient use in March 2023. Findings include: 1. Review of the laboratory's 2023 and 2024 STRECK STATS Quality control reports (lab account # 08803) revealed two Hematology instrument serial numbers: 031215-006448 in January 2023, then 030722-010486. 2. An interview with the lab manager at approximately 11:00 am confirmed the laboratory received a new Medonic Hematology Analyzer in March of 2023. 3. Review of the laboratory's instrument validation records revealed instrument set-up, and instillation of the new Medonic Hematology instrument (Serial #030722-010486) on 3/21/23. The start-up documentation included precision, carryover, calibration, confirmation of Quality</p>

Control values, linearity, along with 20 comparison samples, and 20 normal range samples. The validation documentation lacked evidence of laboratory director evaluation or review of the verification studies. 4. In an exit interview on 1/10/25 at approximately 12:4 with the nurse manager and lab manager, the above findings were confirmed.