

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0221934	(X3) Date Survey Completed 06/20/2018
Name of Provider or Supplier Virginia Pediatric Group	Street Address, City, State 8316 Arlington Blvd #300, Fairfax, 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	The Virginia Department of Health's Office of Licensure and Certification conducted an announced CLIA recertification survey at Virginia Pediatric Group, Ltd on June 20, 2018. The laboratory was surveyed under 42 CFR part 493 CLIA Requirement. Specific deficiencies cited are as follows:
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, quality control (QC) package insert, QC records and an interview, the laboratory failed to follow manufacturer's instructions to confirm recovered QC values are within the expected results or establish new laboratory means before the current control lots expire. Record review was from June 2016 to June 2018. Findings include: 1. Review of the laboratory's procedure manual revealed no procedure for the verification of Coulter 4C QC utilized for the Coulter AcT diff. 2. Review of the Coulter 4C QC package insert revealed manufacturer's instructions that state: "Before your current cell control lot(s) expire perform the following on your new lot(s): Confirm that recovered values are within the TABLE OF EXPECTED RESULTS or establish your own laboratory mean." 3. Review of laboratory's Coulter AcT diff QC records from June 2016 to June 2018 revealed no records of new lot numbers of QC being confirmed prior to current lot numbers of quality control expiring. 4. An interview with the Technical Consultant at approximately 12:15 PM on 6/20/18 confirmed that the laboratory failed to verify new lot numbers of Coulter 4C quality control prior to the expiration of current lot numbers.</p>

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on a laboratory tour, review of the Beckman Coulter 4C control package insert, and an interview, the laboratory failed to ensure that three (3) of three (3) hematology control (QC) vials in use were within the manufacturer's expiration date. Findings include: 1. During a laboratory tour at approximately 10:15 AM on 6/20/18, it was noted that three (3) of three (3) vials of Beckman Coulter 4C QC were opened and stored in the refrigerator. The open vials were: Abnormal Low (lot number 062300 expiration date 6/22/18); Normal (lot number 070000 expiration date 6/25/18); Abnormal High (lot number 081800 expiration date 6/23/18). When asked, the technical consultant confirmed the open vials were in use for the AcT Diff. The inspector asked when the testing personnel opened the control vials. The technical consultant stated: "The vials were put in use on 5/10/18. Our new controls should be here any day now. We had trouble with our shipment this month." The inspector noted that three (3) of three (3) vials did not have the "date of use" on the vials. The surveyor inquired what the protocol for labeling QC was and how the lab could confirm how long the the three (3) QC vials had been opened and in use. The technical consultant stated, "The QC box is tabled with the date of use." The surveyor observed the hand-written date of "5/10/18" on the outside of the Coulter 4C QC box. 2. Review of the Beckman Coulter QC package insert revealed manufacturer stability and storage instructions that state: "Open vial stability (Days) 35. **Assumes that the Instructions for Use section of the package insert is performed a maximum of 31 times within 35 days." 3. During an interview with the technical consultant at approximately 10:15 AM on 6/20/18, the technical consultant confirmed that the laboratory failed to ensure that the QC materials listed above were not used beyond their expiration date.