Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 49D1052366	**(X3) Date Survey Completed** 06/13/2018
Name of Provider or Supplier Pediatric Partners Of Stafford, Pc	**Street Address, City, State** 110 Soaring Eagle Drive, Stafford, 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 Partners of Stafford, PC on June 13 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:
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the hematology instrument performance verification documentation, manufacturer's user guide instructions, patient test logs, and an interview, the laboratory director (LD) failed to evaluate and verify the normal values for Complete Blood Count (CBC) testing prior to reporting two thousand two hundred ninety-three (2,293) patient CBC panels from June 5, 2016 to the date of the survey, June 13, 2018. Findings include: 1. Review of the laboratory's instrument validation records revealed a new hematology analyzer installation, by a Horiba field service technical specialist, occurred on 6/5/16. The inspector found no record of a CBC patient normal value (reference range) validation for the new Horiba Micros 60 (Serial Number 603CS95729). The inspector requested to review documentation that the LD validated the new Horiba analyzer's patient normal value ranges prior to patient testing. No documentation was available for review. 2. Review of the Horiba Users Guide for new instrument installation revealed instructions "The patient Reference

	Range must be validated by the Lab Director". The manufacturer provided instructions and data logs for the client to perform prior to patient testing. 3. Review of the patient test logs revealed that the lab had reported two thousand two hundred ninety-three (2,293) CBC reports from 6/5/16 to the date of the survey on 6/13/18. 4. In an interview with the nurse manager and primary testing personnel at approximately 1:45 PM, it was confirmed that the LD failed to evaluate and validate the patient reference range for CBC testing prior to reporting patient results from the new Micros 60 hematology instrument as outlined above.
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 instrument maintenance records, manufacturer's operations manual, and interviews, the laboratory failed to document hematology instrument weekly preventative maintenance for eighty-five (85) of one hundred four (104) weeks in the reviewed timeframe of June 2016 to the date of the survey on 6/13/2018. Findings include: 1. Review of the laboratory's Horiba Micros 60 hematology maintenance logs revealed a preventative maintenance procedure for Concentrated Cleaning Cycle listed as "perform on a weekly basis". The inspector noted that the available logs from 6/5/16 (the date of the analyzer's installation) to 2/1/18, a total of eighty-five (85) weeks, revealed no weekly maintenance was documented as performed. The inspector requested to review the missing documentation. The primary testing personnel stated "A former employee had been assigned to document and retain those records and we cannot locate them. We do have documentation from February 2018 up to now." 2. Review of the Horiba Micros 60 Operations Manual revealed manufacturer's instructions which state: "a concentrated cleaning cycle must be performed with Minoclair solution once weekly". 3. In an interview with the nurse manager and primary testing personnel at approximately 1:45 PM, it was confirmed that the laboratory failed to document performance of the Horiba hematology weekly Concentrated Cleaning Cycle for the timeframe outlined above in calendar years 2016, 2017, and up to February of 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 the procedures and policies, hematology calibration records, and interviews, the laboratory failed to document Horiba Micros 60 calibration procedures for hematology Complete Blood Count (CBC) patient testing according to their written procedure in calendar year 2017. Findings include: 1. Review of the laboratory's procedure manual revealed a Quality Assurance (QA) policy that outlined to calibrate CBC testing on the Horiba Micros 60 hematology analyzer at a frequency of every six (6) months. 2. Review of the Micros 60 hematology instrument calibration documentation from July 2016 to the date of the inspection on 6/13/18, a total of twenty-three (23) months, revealed a lapse in the six month calibration: The inspector noted documentation that calibration procedures were performed once in calendar year 2017 (on 6/26/17). No other calibration documentation in 2017 was available for review. The inspector requested to review additional calibration records for 2017. The primary testing personnel stated, "We cannot find any other documentation of a calibration in 2017". The inspector noted that the lab documented a calibration on 5/2/18, a four (4) month lapse in the protocol. 3. In an interview with the nurse manager and primary testing personnel at approximately 1:45 PM, it was confirmed that the laboratory failed to document calibration procedures for CBC testing, in calendar year 2017, according to their written QC policy.