Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1052366	10/27/2020
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Partners Of Stafford, Pc	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 on-site CLIA recertification survey was conducted at Pediatric Partners of Stafford on October 27, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview on 09/22/2020 and virtual record review conducted on 10/21/2020. The laboratory was surveyed under 42 C.F.R. part 493 CLIA Regulations. The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D5400 - 42 C.F.R. 493.1250 Condition: Analytic Systems and D6000 - 42 C.F.R. 493.1403 Condition: Moderate complexity laboratory director.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records, lack of documentation, and an interview, the laboratory failed to document remedial /corrective action for one (1) unacceptable PT score out of seven (7) Hematology PT event results reviewed from July 2018 to October 2020. Findings include: 1. Review of the laboratory's Medical Laboratory Evaluation (MLE) PT documentation for 2018 (Events 2-3), 2019 (Events 1-3), and 2020 (Events 1-2), a total of 7 events, revealed no corrective action documented for the following unsatisfactory performance: 2020 Event 1- Cell Identification or White Blood Cell Differential scored at seventy-three percent (73%). The inspector requested to review corrective/remedial action for the

	unsatisfactory PT performance outlined above. The laboratory provided no documentation for review. 2. In an interview with the nurse manager at approximately 9:45 AM on October 27, 2020, the findings were confirmed.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of the laboratory's policy and procedure manual, manufacturer's operators guide, maintenance records, calibration records, and interviews, the laboratory failed to: 1. document hematology instrument weekly preventative maintenance for the Horiba Micros 60 (see D5429), REPEAT DEFICIENCY; 2. document Horiba Micros 60 calibration procedures according to their written policy (see D5437) REPEAT DEFICIENCY.
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: REPEAT DEFICIENCY 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 fifty-eight (58) of one hundred twenty (120) weeks reviewed from July 2018 until the date of the survey on October 27, 2020. Findings include: 1. Review of the laboratory's Horiba Micros 60 hematology maintenance logs revealed a "Weekly Maintenance" procedure "Perform Concentrated Cleaning". The surveyor noted the available logs from July 2018 until the date of the survey on October 27, 2020, a total of 120 weeks, revealed 58 weeks where no weekly maintenance was documented as performed. The surveyor requested to review the missing documentation of the weekly maintenance. The laboratory provided no documentation to review. 2. Review of the Horiba Micros Operations manual revealed manufacturer's instructions which stated, "a concentrated cleaning cycle must be performed with Minoclair solution once weekly". 3. In an interview with the nurse manager at approximately 10:15 AM on October 27, 2020, the findings were confirmed.
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: REPEAT DEFICIENCY Based on review of policy and procedure manual, Horiba Micros 60 calibration records, and interviews, the laboratory failed to document Horiba Micros 60 calibration procedures for hematology Complete Blood Count (CBC) testing according to their written policy from November 26, 2018 until October 2, 2020. 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 at a frequency of every six (6) months. 2. Review of the laboratory's 2018, 2019 and 2020 calibration records revealed calibrations were performed on the Horiba Micros 60 on 11/26/2018, 8/8/2019, 2/6/2020 and 10/2/2020. The surveyor requested additional documentation for calendar year 2018, 2019 and 2020 demonstrating calibration for the Horiba Micros every 6 months. The laboratory provided no additional calibration documentation between 11/28/2018 to 8/8/2019 and 2/6/2020 to 10/2/2020. 3. In an interview with the nurse manager at approximately 9:50 AM on October 27, 2020, the findings were confirmed.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of policies and procedures, manual, manufacturer operator's guide, maintenance records, and calibration records, Proficiency Testing (PT) records, Quality Assurance (QA) records, lack of documentation, and interviews, the laboratory director (LD) failed to: 1. document evaluation of and corrective action for unacceptable analyte scores (see D6018); 2. ensure corrective action plan was followed and remedial action was documented for unacceptable PT scores (see D6019); 3. ensure QA policies were maintained from July 2018 until date of the survey on October 27, 2020 (see D6021)
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 a review of the laboratory's proficiency testing (PT) records, lack of documentation, and an interview, the laboratory director failed to document evaluation of and corrective action for seven (7) unacceptable analyte scores noted on two (2) of seven (7) PT events reviewed from July 2018 to October 2020 . Findings include: 1. Review of the laboratory's Medical Laboratory Evaluation (MLE) PT documentation for 2018 (Events 2-3), 2019 (Events 1-3), and 2020 (Events 1-2), a total of 7 events, revealed a lack of evidence of evaluation for the following unacceptable hematology analyte scores: Hematocrit: HD-1 resulted 52.8 (acceptable range of 46.6-52.7) on 2020 MLE M1; White Blood Cell Count: HD-9 resulted 5.7 (acceptable range of 17.7-24.0) on 2020 MLE-M2; Red Blood Cell Count: HD-9 resulted 6.20 (acceptable range of 5.32-6.01) on 2020 MLE-M2; Platelet Count: HD-9 resulted 170 (accepted range of 383-640) on 2020 MLE-M2; Lymphocytes: HD-9 resulted 31.4 (accepted range 6.5-15.7) on 2020 MLE-M2; Mono/Mid/Mixed/MCR: HD-9 resulted 24.1 (accepted range 3.2-7.3) on 2020 MLE-M2; Granulocytes/Neut: HD-9 resulted 44.5 (accepted range 80.5-87.0) on 2020 MLE-M2. a total of 7 unacceptable analyte scores. The surveyor requested to review documentation the laboratory's evaluation of the unacceptable results outlined above. The laboratory provided no documentation for review. 2. In an interview with the nurse manager at approximately 9:45 AM on October 27, 2020, the above findings were confirmed
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records, lack of documentation, and an interview, the laboratory director failed to ensure a corrective action plan was followed and remedial action documented for one (1) unacceptable PT score out of seven (7) Hematology PT event results reviewed from July 2018 to October 2020 (see D2128).
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, Quality Assurance (QA) records, Proficiency Testing records (PT), Horiba Micros 60 instrument maintenance records, calibration records, lack of documentation and interviews, the laboratory director (LD) failed to ensure that the QA policies were maintained from July 2020 until October 2020. Findings include: 1. Review of the laboratory's policy and procedure manual revealed a written and approved QA policy that included: a. a "Triannual Quality Assurance Checklist" with the statement "Answer all questions Y (yes), N (No), or NA (not applicable)" to be performed by the staff and reviewed by the Laboratory Director. The QA check list included a "Proficiency Testing" section that stated "Failed PT evaluated and remedial action documented." and; b. a "Monthly Quality Assessment Review" to be performed by the staff and reviewed by the Laboratory Director. The QA checklist included an "Analytical Phase" section with a question "Is the required maintenance performed? Yes or No." 2. Review of the laboratory's PT records revealed no documentation of the remedial action taken for unsatisfactory and unacceptable results for the 2020 Medical Laboratory Evaluation PT events M1 and M2. (See D2128, D6018 and D6019.) 3. Review of the laboratory's available "Triannual Quality Assurance Checklist" from March 2020 until October 2020 revealed the statement "Failed PT evaluated and remedial action documented." completed as "Y" and reviewed by the Laboratory Director for the months of April 2020 and August 2020. There was a lack of documentation of the remedial action taken for the 2020 Medical Laboratory Evaluation PT events M1 and M2. (see D2128, D6018 and D6019.) 4. Review of the laboratory's Horiba Micros 60 maintenance records revealed a lack of documentation the instruments weekly maintenance for fifty-eight (58) of one hundred twenty (120) weeks from July 2018 until the date of the survey on October 27, 2020 (see D5429 REPEAT DEFICIENCY). 5. Review of the laboratory's available "Monthly Quality Assessment Review" documentation from July 2018 until the date of the survey on October 27, 2020 revealed the question "Is the required maintenance performed?" completed as "Yes" and reviewed by the Laboratory Director for thirty (30) of 30 months reviewed from July 2018 until September 2020. 6. In an interview with the nurse manager manager at approximately 10:30 AM on October 27, 2020, the findings were confirmed.