Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0665213	10/01/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric & Adolescent Health Partners	8719 Forest Hill Ave, Bon Air, 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 and Adolescent Health Partners on October 1, 2019 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:
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of hematology proficiency testing (PT) records, procedure manual, and an interview, the laboratory failed to document a review of PT results /performance for Complete Blood Count (CBC) for three (3) out of six (6) events in the twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's Wisconsin State Laboratory of Hygiene (WSLH) hematology PT records (2017 3rd event, 2018 1st-3rd events, 2019 1st-2nd events) revealed no documentation of result review for: 2018 Event 1, 2018 Event 2, 2018 Event 3. The inspector requested to review documentation of result review for the CBC PT events outlined above. No records or laboratory director signatures of review were available. The nurse laboratory administrator stated at approximately 1:30 PM, "We have tried to amend this oversight for PT results this year". 2. Review of the procedure manual revealed that the laboratory utilized their vendor's PT procedure (WSLH) that stated "upon receipt, the results will be reviewed by the lab director and staff". 3. In an exit interview with the nurse laboratory administrator at approximately 3:00 PM, the above findings were confirmed.
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 manufacturer's operations manual, hematology analyzer maintenance records, and an interview, the laboratory failed to document performance of required twice annual Abbott Emerald Hematology instrument maintenance in calendar year 2018. Findings include: 1. Review of the Abbott Emerald Operations Manual revealed manufacturer's instructions to "perform Lubricating Syringe Pistons maintenance procedure twice annually". 2. Review of the laboratory's Emerald hematology maintenance logs from October 2017 to January 2019, revealed one maintenance record of piston syringe lubrication (dated 1/18/18). The inspector requested to review additional documentation of the piston syringe maintenance. No other records were available. The nurse laboratory administrator stated, at approximately 2:00 PM, "We replaced the Emerald instrument with a Medonic M Series in January 2019. We did not use the Abbott manufacturer's maintenance charts to document our maintenance. We used our own daily log sheets. We relied on the field service technicians to either remind us or to perform the piston procedures when it was required. I have checked emails for the maintenance communication but cannot find any other records for the piston syringe procedure". 3. In an exit interview with the nurse laboratory administrator at approximately 3:00 PM, the above findings were confirmed.