Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2053354	11/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
Preferred Pediatrics At Courthouse	9755 Courthouse Road, Suite 101, Spotsylvania, 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 Preferred Pediatrics at Courthouse Road on November 7, 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:
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) documentation, and an interview, the laboratory failed to retain attestation statements signed by the laboratory director (LD) and testing personnel for one (1) of six (6) events reviewed. Findings include: 1. Review of the laboratory's Medical Laboratory Evaluation (MLE) 2017 and 2018 hematology PT documentation, a total of 6 events, revealed no signed attestation statements for: 2018 Event M3. The inspector requested to review the LD and testing personnel attestation documentation for the event listed above. No documentation was available for review. 2. In an interview with the clinical coordinator, at approximately 1:00 PM, it was confirmed that the laboratory failed to retain copies of the PT attestation statement as outlined above.

D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on a review of policies and procedures, a laboratory tour, and an interview, the laboratory failed to process three (3) of 3 patient complete blood count (CBC) samples using two (2) positive unique patient identifiers on the date of the inspection, November 7, 2018. Findings include: 1. Review of the laboratory's policy and procedure manual revealed a specimen collection policy to utilize two (2) positive identifiers for patient samples through all phases of testing. 2. During a laboratory tour with the clinical coordinator and primary testing personnel, at approximately 11: 30 AM, the inspector observed 3 patient CBC samples in the the hematology testing area. The inspector noted: Sample 1: CBC sample labeled with two initials (AS), Sample 2: CBC sample had no identification, Sample 3: CBC sample had no identification. 3. In an interview with the clinical coordinator, at approximately 1:00 PM, it was confirmed that the laboratory failed to follow their policy to label patient samples with positive unique identifiers on the date of the inspection, 11/7/18, 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 manufacturer's Operations Manual, hematology instrument maintenance records, and an interview, the laboratory failed to perform and document hematology instrument semi-annual maintenance from November 2016 to December 2017. Findings include: 1. Review of the Abbott Emerald Operations Manual revealed manufacturer's instructions to "perform the Lubricating Syringe Pistons procedure semi-annually". 2. Review of the laboratory's Abbott hematology maintenance logs from November 2016 to the date of the survey, 11/7/18, revealed no semi-annual maintenance documented from 11/1/16 to 1/5/18. The inspector requested to review documentation of the maintenance for calendar year 2017, noting that a field service technician performed the procedure during a preventative maintenance check on 1/6 /18 and again on a service call on 9/14/18. No additional documentation of the maintenance was available for calendar year 2017. 3. In an interview with the clinical coordinator, at approximately 1:00 PM, it was confirmed that the laboratory failed to perform and document the Abbott Emerald semi-annual preventative maintenance for the thirteen (13) month period of November 2016 to December 2017.