

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2053354	(X3) Date Survey Completed 11/19/2024
Name of Provider or Supplier Preferred Pediatrics At Courthouse	Street Address, City, State 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 on November 19, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiency cited is as follows:
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's Cell-Dyn Emerald hematology analyzer's calibration records, lack of documentation, and interview, the laboratory failed to retain the "Cell Dyn 18 Plus Calibrator" manufacturer's assay information insert documenting acceptable calibration limits for one (1) of four (4) lot numbers from January 2023 up to the date of the survey on November 19, 2024. The findings include: 1. Review of the laboratory's Cell -Dyn Emerald hematology analyzer's calibration records from January 2023 up to the date of the survey on November 19, 2024 revealed the laboratory received and used 4 lot numbers of the "Cell Dyn 18 Plus Calibrator". 2. Further review of the calibration documentation revealed the lack of documentation of the "Cell Dyn 18 Plus Calibrator" manufacturer's assay information insert for lot number 4148 exp 07/10/2024. The surveyor requested to review the package insert for lot number 4148. The laboratory provided no documentation for review. 3. In an exit interview with the primary testing personnel on November 19, 2024, at 12:15 PM, the findings were confirmed.</p>