

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  15D2086917	<b>(X3) Date Survey Completed</b>  09/10/2024
<b>Name of Provider or Supplier</b>  Kids First Pediatric Specialists Georgetown	<b>Street Address, City, State</b>  5300 Sr 64, Ste 105, Georgetown, IN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to label open and expiration dates on Quality Control (QC) vials used for five of five analytes (white blood cell count (WBC), red blood cell count (RBC), hemoglobin (HGB), hematocrit (HCT), platelet (PLT), differential blood count (Diff)) tested on the Cell-Dyn Emerald analyzer (serial number 030423-010706). Findings include: 1. During laboratory tour on 9/10/2024 at 10:11 am, the current (opened) QC, lot number 4176, was observed to be missing open date and new expiration date. 2. In an interview on 9/10/2024 at 10:39 am, SP-4 confirmed that open date and exp date are not being documented on QC vials or in a log. 3. Package insert "Cell-DYN 18 Plus Control" ref 09HG9-01, for QC Lot number 4176, states "8 Consecutive Day Open-Tube Stability". 4. Policy titled "Quality Control for Non-waived testing", revised 9/21/2023, under Storage and Handling E. reads, "Controls MUST be labeled with the opening date and initialed by TP whom opened." 5. Annual test volume for hematology testing is 1,668.</p>