

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D0922807	<b>(X3) Date Survey Completed</b>  08/03/2023
<b>Name of Provider or Supplier</b>  Children's Faith Pediatrics	<b>Street Address, City, State</b>  1341 Branton Boulevard Ste 102, Knoxville, TN	
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 of the laboratory, review of manufacturer control package insert, and interview with the office manager, the laboratory failed to label Complete blood Count (CBC) controls with open date and corrected expiration date on the date of the survey (three of three controls observed). The findings include: 1. Observation of the laboratory on 08.03.2023 at 7:15 a.m. revealed the Beckman Coulter DxH500 instrument (serial # BD040010) in use for patient testing for CBC. Controls were observed in use that were not labeled with open date or corrected expiration date (DxH500 Series Control, Lot numbers 352314911, 362314912, and 372314913). 2. Review of the Beckman Coulter control package insert revealed that controls are good for 16 days after opening. 3. Interview with the office manager on 08.03.2023 at 10:30 a.m. confirmed the laboratory failed to label three of three controls with open date and corrected expiration date on the date of the survey (08.03.2023).</p>