

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0310262	(X3) Date Survey Completed 06/12/2024
Name of Provider or Supplier Children's Diagnostic Center	Street Address, City, State 7550 Goodwin Road, Chattanooga, TN	
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
D5415	<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 laboratory observation, review of the manufacturer's package insert, and staff interview, the laboratory failed to label three of three CBC control vials with a corrected expiration date after opening. The findings include: 1. Observation of the laboratory on 06/12/24 at 09:30 a.m. revealed the Beckman Coulter DxH 520 CBC instrument (SN BD050366) used for performing patient testing for CBC w/Diff. The controls (three of three) were labeled with an open date of 06/05/24 but no corrected expiration date. Lot numbers observed were 352416011, 352416012 and 352416013. 2. A review of the manufacturer package insert revealed the controls were stable for 16 days after opening. 3. The practice manager, lab manager and testing personnel confirmed the survey findings during interview on 06/12/24 at 12:15 p.m.</p>