

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D1087535	(X3) Date Survey Completed 10/29/2024
Name of Provider or Supplier Children's Group, Pc, The	Street Address, City, State 604 N 5th Street, Hartsville, SC	
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	D000 An onsite announced CLIA recertification survey was conducted on October 29, 2024, by the South Carolina Department of Public Health's Bureau of Nursing Homes and Medical Services at the clinical laboratory of The Children's Group of Hartsville. The laboratory was found to be out of compliance with 42 CFR Part 493, CLIA Requirements for Laboratories. The following is a list of STANDARD level deficiencies cited: D5415
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 direct observation, document review, and staff interview, the laboratory failed to document the opening date for in use urinalysis and hematology quality control materials. Findings included: 1. During a tour of the clinical laboratory on 10/29/2024 at 12:30pm, the surveyor observed quality control bottles which did not have an open date documented on the bottle that were currently in use. 2. The quality control bottles were as follows: a. Sysmex hematology control lot # 42190710 low control expiration date (exp) 11/13/2024. b. Sysmex hematology control lot # 42190711 medium control exp 11/13/2024 c. Sysmex hematology control lot # 42190712 high control exp 11/13/2024 d. Quantametrics urinalysis control lot # 225841 normal control exp 11/30/2024 e. Quantametrics urinalysis control lot # 225842 abnormal control exp 11/30/2024 3. In an interview with the testing personnel 1 (TP1) and the Clinical Consultant (CC) on 10/29/2024 at 12:30pm, the findings were confirmed.</p>