

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1086599	(X3) Date Survey Completed 12/19/2024
Name of Provider or Supplier Childrens Medicine Pc	Street Address, City, State 1500 Peachtree Industrial Boulevard Suite 250, Suwanee, GA	
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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on December 19, 2024. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on the laboratory tour, review of temperature logs and hematology reagents storage manufacturer's recommendations, the laboratory failed to monitor temperatures for the hematology reagents storage room in 2023 thru the date of survey, 12/19/2024. Findings: 1. A review of the Sysmex CellPack reagent reference #CPK-310A package labelling, revealed the required storage at +1*C - +30*C. The reagent was found stored in a storage room in which the temperature was not being monitored to assure proper storage in 2023 thru the date of survey. 2. An interview with the technical consultant (TC)(TP#5 CMS 209) and (TP#3 CMS 209) in the break room at approximately 12:30 PM on 12/19/2024 confirmed the above findings.</p>
D6014	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii)</p>

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on personnel records review and staff interviews, the laboratory director failed to ensure that ALL Quality Assurance (QA) guidelines were followed to identify and fix problems in the laboratory in 2023 thru the date of survey as required by Clinical Laboratory Improvement Amendments (CLIA). Findings: 1. Personnel documents review revealed the lab director had no proof that annual competencies were performed on the technical consultant (TC) (TP # 5 CMS 209) in 2023 thru the date of survey, 12/19/2024. 2. An interview with the laboratory's (TC) (TP#5 CMS 209) and (TP#3 CMS 209) in the lab break room on 12/19/2024, at approximately 12:45 PM, confirmed the lab director failed to ensure proper oversight of the laboratory in 2023 thru the date of survey.