

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0260802	(X3) Date Survey Completed 05/29/2024
Name of Provider or Supplier Children's Medical Group	Street Address, City, State 1875 Century Blvd Ne Suite 150, Atlanta, 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 recertification survey was performed on , May 29, 2024. The facility was found to be NOT in compliance with all applicable CLIA requirements for specialties /subspecialties for 42 CFR.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the College of American Pathologist (CAP) Proficiency Testing Provider (PT) and staff interview, the laboratory failed to verify the accuracy of testing for the Specialty Chemistry- Subspeciality (Routine) -Analyte (Direct Bilirubin(DBili). In the year 2022, events A,B, and C, for the year 2023, events A, B, C. Findings: 1, Review of the CAP, PT documents for DBili (2022 events A,B,C) and (2023 events A,B,C) the laboratory received a score of NOT GRADED for insufficient peer group data. The laboratory failed to verify the accuracy of the analyte (DBili.) 2. Interview with the supervisor, on 05/29/2024, at approximately 1 pm in the doctor's office, confirmed the statement above.</p>
D6013	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</p> <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)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance</p>

characteristics of the method;

This STANDARD is not met as evidenced by:

Based on review of the College of American Pathologist (CAP) Proficiency Testing (PT) provider and staff interview the Laboratory Director(LD) failed to ensure that Specialty- Chemistry, Subspecialty (General), Analyte(Direct Bilirubin (DBILI)) was verified twice a year after receiving NOT GRADED results for 2022 events A,B,C, and 2023 events A,B,C. Findings: 1, Review of the CAP, PT documents for DBili (2022 events A,B,C) and (2023 events A,B,C) the laboratory received a score of NOT GRADED for the insufficient peer group data. The LD failed to monitor and verify the accuracy of the analyte - DBili. 2. Interview with the supervisor, on 05/29/2024, at approximately 1 pm, in the doctor's office, confirmed the statement above.