Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0260802	06/02/2026
Name of Provider or Supplier	**Street Address, City, State**	
Children's Medical Group	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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on June 2, 2026. 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:
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation during the laboratory tour, review of the Standard Operating Procedures, and interview with the Clinical Team Lead, the laboratory director failed to ensure that safety procedures were established, accessible, and followed. Findings: 1. A review of the Standard Operating Procedures revealed there was no written laboratory safety policy. 2. Observation during the laboratory tour, revealed TP #4 (CMS-209) handling a capillary tube, containing blood, without wearing gloves or a laboratory coat. 3. Observation during the laboratory tour revealed the eyewash station was located on a dirty sink that contained current patient urine specimens. 4. An interview with the Clinical Team Lead, in the conference room, on June 2, 2026, at 12:00 p.m., confirmed that a written safety policy was not included in the Standard Operating Procedures.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify

	failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of quality assessment, quality control records and interview with the Clinical Team Lead, the Laboratory Director failed to ensure quality assessment and quality control programs were maintained. Findings: 1.A review of Quality Assessment records revealed there was no documented quality assessment log completed for 2025 and 2026. 2. A review of Quality Control records revealed daily quality control was performed for all chemistry and complete blood count testing; however, there was no documentation of monthly review of the quality control records by the Laboratory Director. 3. An interview with the Clinical Team Lead, in the conference room, on June 2, 2026, at 12:00 p.m., confirmed that quality assessment logs had not been completed and also the failure of a monthly review of quality control records by the Laboratory Director.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the Clinical Team Lead, the Laboratory Director failed to ensure initial competency assessments were documented for all Testing Personnel (TP). Findings: 1. A review of Testing Personnel records revealed that 2 of 4 testing personnel, TP #3 (CMS-209) and TP #4 (CMS-209), did not have documented initial competency assessments. Specifically, TP #3 did not have a documented 2025 initial competency assessment, and TP #4 did not have a documented 2026 initial competency assessment. 2. Interview with the Clinical Team Lead in the conference room on June 2, 2026, at 12:00 p.m., confirmed that the initial competency assessments were not performed for TP #3 (2025) and TP #4 (2026).
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on review of the Standard Operating Procedures and interview with the Clinical Team Lead, the laboratory director failed to ensure that approved procedures were signed and dated. Findings: 1. A review of the Standard Operating Procedures revealed that the laboratory director had not signed or dated the procedure manual prior to placing in use, March 14, 2024. 2. Interview with the Clinical Team Lead in the conference room on June 2, 2026, at 11:30 a.m., confirmed the laboratory director had not reviewed, signed, and dated the procedure manual since March 14, 2024.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(14) (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the Standard Operating Procedures and interview with the Clinical Team Lead, the laboratory director failed to specify, in writing, the duties and responsibilities for all laboratory personnel. Findings include: 1. Review of the Standard Operating Procedures revealed that duties and responsibilities were documented for the Laboratory Director and Testing Personnel positions; however, the Technical Consultant and Clinical Consultant positions did not have documented duties and responsibilities. 2. Interview with the Clinical Team Lead in the conference room, on June 2, 2026, at 12:00 p.m., confirmed the Standard Operating Procedures did not include documented duties and responsibilities for the Technical Consultant and Clinical Consultant positions.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the Clinical Team Lead, the Laboratory Director failed to ensure semiannual competency assessments were documented for all Testing Personnel (TP). Findings: 1. Review of Testing Personnel records revealed that 1 of 4 testing personnel, TP #3 (CMS-209), did not have a documented 2025 semiannual competency assessment. 2. Interview with the Clinical Team Lead in the conference room on June 2, 2026, at 12:00 p.m., confirmed that the 2025 semiannual competency assessment had not performed for TP #3 (CMS-209).
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the Clinical Team Lead, the Laboratory Director failed to ensure annual competency assessments were documented for all Testing Personnel (TP). Findings: 1. Review of Testing Personnel records revealed that 2 of 4 testing personnel did not have documented annual competency assessments completed for 2025 and 2026 to date. 2. Interview with the

	Clinical Team Lead in the conference room on June 2, 2026, at 12:00 p.m., confirmed annual competency assessments for TP 1 (CMS-209) and TP 2 (CMS-209) were not performed during the aforementioned years.