Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0260802	07/28/2022
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 July 28, 2022. 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:
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual and interview with Testing Personnel. The Laboratory failed to have a policy and procedure in place for complaint investigations. The Finding include: 1. SOP document review revealed that the laboratory did not have a policy and procedure for complaint investigations, during the time of the survey. 2. During an interview with Testing Personnel#1(CMS-209) on July 28, 2022 at approximately 3:25 PM, in the front conference room, confirmed that the laboratory did not have a SOP in place for complaint investigations.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

	This STANDARD is not met as evidenced by: Based on the review of the Standard Operating Procedure (SOP) records review and staff interview. The laboratory failed to establish a competency policy and procedure. The Findings include: 1. The laboratory failed to establish a written policy and procedure to assess competency based on the position responsibilites on an initial, semi-annual, and annual bases. 2. An annual competency assessment was not performed for the following staff: Testing Personnel#1(CMS-209) and Testing Personnel#3(CMS-209). 3. An annual competency assessment was performed for the following staff, but the evaluation was not signed by the Laboratory Director or the Testing Personnel: Testing Personnel#3(CMS-209)- Initial competency for 2022, Testing Personnel#5(CMS-209)-Initial competency for 2022. 4. During an interview on July 28, 2022 with Testing Personnel#1(CMS-209) at approximately 2:25 PM, confirmed the failure to establish a competency policy and procedure.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on the review of a laboratory policy and procedure manual (SOP) and staff interview. The laboratory failed to have a policy and procedure for complaint investigations. Findings include: 1. SOP document review revealed there was no complaint investigations policy and procedure, available at the time of survey on July 28, 2022. 2. During an interview on July 28, 2022 with Testing Personnel#1(CMS-209) in the conference room at approximately 2:30 PM, confirmed the lack of a complaint investigations policy and procedure for the laboratory.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on quality assessment (QA) document review and staff interview, the laboratory failed to document quality assessment activities as required. The Findings include: 1. Laboratory QA document review revealed the lack of a QA checklist documentation from 2020 to the date of the survey, July 28, 2022. 2. During an interview with the Testing Personnel#1 (CMS 209) on July 28, 2022 at 10:25 AM in the front conference room, confirmed the lack of a QA checklist documentation from 2020, 2021, and thus far 2022.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250

	Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the maintenance document review, the laboratory failed to document maintenance for Sysmex. The laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems as required for Hematology and Chemistry. Findings include: For details refer to D5429, D5431, and D5441
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the tour of the lab, observation, record review and interview, the laboratory failed to maintain required calibration records for the centrifuge. The Findings include: 1. Observation during the lab tour revealed the Beckman Coulter StatSpin centrifuge(Serial no.1710M90101899) was last calibrated on January 13, 2018. The requirement for this centrifuge is to be calibrated annually. The manufacturer recommends that the Beckman Coulter StatSpin centrifuge is calibrated every 12 months. 2. During an interview with Testing Personnel #1 (CMS 209) on July 28, 2022, in the lab at approximately 2:55 PM, confirmed the centrifuge had not been calibrated since January 13, 2018.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of records and staff inteview, the laboratory failed to document required maintenance per manufacturer instructions for the Hematology analyzer. Findings include: 1. Maintenance document review revealed there was no quarterly maintenance performed for the Sysmex from 2020 up to the current date of the survey, July 28, 2022 for hematology testing. 2. During an interview with Testing Personnel#1(CMS-209) on July 28, 2022, in the front conference room at approximately 3:40 PM, confirmed the lack of quarterly maintenance for the Sysmex for hematology testing from 2020 to the current date of the survey, July 28, 2022.

D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Quality control (QC) document review and staff interview, the lab failed to monitor over time the accuracy and precision of test performance for Chemistry test on the Piccolo. The Findings include: 1. QC document review revealed that the lab failed to monitor and perform external controls for the Chemistry test on the Piccolo from 2020 to the survey date, July 28, 2022. 2. During an interview with Testing Personnel#1(CMS-209) on July 28, 2022 at approximately 2:20 PM, in the front conference room, confirmed that the laboratory did not run external controls for the Chemistry test on the Piccolo.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on Standard operating procedure (SOP) review and staff interview, the laboratory failed to develop a corrective action prodecure for the laboratory. The Findings include: 1. SOP review reveals the laboratory failed to develop and implement a corrective action procedure for the laboratory. 2. During an interiew with Testing Personnel#1(CMS-209) on July 28, 2022 at approximately 12:20 PM in the front conference room, confirmed the lack of developing a corrective action procedure for the laboratory.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: Based on review of the laboratory records, procedure manual (SOP), and staff interview, the laboratory director failed to ensure that the external quality control (QC) and quality assessment(QA) programs are established and maintained to identify failures in the laboratory. Findings include: 1. Review of the SOP revealed the lack of a written Quality Assessment (QA) program for the overall laboratory from 2020 to the date of the survey, July 28, 2022. 2. Review of the laboratory's records revealed no documentation of pre-analytic, analytic, or post-analytic monitors for the overall laboratory. 3. No external QC documents were available to review on hematology testing for the Sysmex, at the time of survey. 4. During an interview with Testing Personnel#1(CMS-209) on July 28, 2022 at approximately 3:45 PM , in the front conference room, confirmed that the laboratory did not have records for QA and QC from 2020 to the date of the survey July 28, 2022.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(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 laboratory policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to specify, in writing the duties and responsibilities of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of laboratory testing. Findings include: 1. SOP review revealed the LD failed to have a job description and duties for testing personnel, during the time of the survey. 2. During an interview with Testing Personnel#1(CMS-209) on July 28, 2022 in a front conference room of the building at approximately 2:25 PM, confirmed the SOP did not contain duties and responsibilities policy and procedure.