Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0924082	04/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Childrens Medical Group	610 Providence Park Drive Suite 201, Mobile, AL	

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
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 a review of Policies and Procedures and an interview with the Technical Consultant, the laboratory failed to establish and follow written policies and procedures to assess the competency of employees. The findings include: 1. A review of the Policies and Procedures revealed a lack of a policy outlining the process of how competency assessments were performed on testing personnel. 2. During an interview on 3/2/2023 at 1:25 PM, the Technical Consultant confirmed the above findings.
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 a review of Policies and Procedures and an interview with the Technical Consultant, the laboratory failed to establish and follow written policies and procedures for Quality Assessment that included the assessment of complaint investigation. The findings include: 1. A review of Policies and Procedures revealed an out-dated Quality Assessment policy which failed to include Complaint

	Investigation as a quality monitor. 2. During an interview on 3/2/2023 at 1:25 PM, the Technical Consultant confirmed the above findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of Policies and Procedures and an interview with the Technical Consultant, the laboratory failed to have a procedure specifying the normal reference ranges for pediatric CBC's (Complete Blood Counts) performed on the Medonic M Series Hematology Analyzer. This was noted from the implementation of the procedure, 2/22/2023, to the date of the current survey, 3/2/2023. The findings include: 1. A review of the Policies and Procedures revealed a page specifying the Medonic M Series Operator's Manual was used as the procedure. This procedure did not include normal CBC reference ranges specific to the pediatric patient population treated at the facility. 2. During an interview on 3/2/2023 at 1:25 PM, the Technical Consultant confirmed the above findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on a review of Maintenance records and interviews with Testing Personnel #1, the laboratory failed to ensure maintenance for the centrifuge (used to process specimens for Neonatal Bilirubin testing) was documented. This was noted from the

	date of the last survey, 12/8/2021, to the date of the current survey, 3/2/2023. The findings include: 1. A review of Maintenance records revealed no documention of maintenance for the laboratory's centrifuge. 2. During an interview on 3/2/2023 at 1: 00 PM, Testing Personnel #1 explained a Quest Laboratory representative came annually to perform maintenance, and retained those records. After reaching out to the Quest Representative, Testing Personnel #1 informed the surveyor no maintenance records were available for review.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of Testing Personnel records and an interview with the Technical Consultant, the Technical Consultant failed to implement and document evaluations that included the six minimal regulatory requirements for assessment of competency for the Medonic M Series Hematology analyzer and the Reichert Bilirubinometer. This was noted for three out of three Testing Personnel from December 2021 to the date of the current survey (03/02/2023). The findings include: 1. A review of Testing Personnel records revealed forms titled "Technical Consultant Evaluation" that included the following criteria: "1. Technical Competence, 2. Quality Controls Records & Compliance, 3. Maintenance Records & Compliance, 4. Proficiency Testing Compliance, 5. Daily Quality Assurance Logs, 6. Patient Lab Records, 7. Lab Policy Manual Compliance, 8. Lab Procedure Manual Compliance, 9. Punctuality on Lab Testing & Records, 10. Cooperation with Lab Administrator/Office Manager/Lab Supervisor". The form failed to include an assessment of "problem solving skills." On 3/27/2023, via email, the Technical Consultant submitted additional competency assessment forms for review, which he stated was provided on-site. On 4/12/2023 at 10:00 AM, the CLIA Supervisor and the CMS Location Representative reviewed these forms for the Medonic-M Series and the Reichert Bilirubinometer. These forms included an "On-Site Visual" of Start-up/Shut Down, Performance of Patient Samples, Daily Quality Control, and Daily and Monthly Maintenance. This form did not address "problem solving skills." 2. During an interview at 12:00 PM on 03/02/2023, the Technical Consultant confirmed the aforementioned form (item in paragraph 1) was used as a competency assessment for Testing Personnel.