Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0305760	12/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Children's Medical Group	3920 Airport Blvd, 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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of the manufacturer's instruction manual, a review of the calibration and calibration verification (C/V) records for the Reichert Bilirubinometer (used for neonatal Bilirubin testing), and an interview with the Technical Consultant, the surveyor determined the laboratory failed to perform C/V's every six months in 2017 and 2018. The findings include: 1. A review of the records for the Reichert Unistat Bilirubinometer revealed Bilirubin was calibrated once every six months (in

	June and December) using the glass calibration cuvette assayed at 20.9 mg/dl (milligrams per deciliter) as per manufacturer's instructions. Analytes calibrated with less than three calibrators must have a calibration verification performed every six months with at least three points to include low-, mid-, and high-range values to verify the reportable range of the Bilirubin results. 2. A review of the Reichert Unistat Bilirubinometer Instruction Manual under, "...6.4 Calibration Verification Two assayed glass cuvettes are provided with the REICHERT UNISTAT Bilirubinometer: 1. ...Calibration Cuvette (assay values range from 19 to 23.9 mg/ml) ... 2. ...High-Level Check Cuvette (assay value approximately 40.0 mg/ml) ... ...[These] glass cuvettes may be used to check the bilirubinometer at the mid and high points of its 0-40 mg/dl measuring range. A sample cuvette ... filled with distilled water may be used to check zero. ...". 3. A review of the Reichert Unistat Bilirubinometer records revealed a C/V was performed 6/12/2017 (reviewed during the previous survey), and then on 12/15/2018 and 6/14/2019. There were no C/V records for the eighteen months between June 2017 and December 2018. 4. During an interview on 12/11 /2019 at 2:25 PM, the surveyor reviewed the above records with the Technical Consultant who confirmed the laboratory had missed performing the C/V's due in December 2017 and June 2018. SURVEYOR ID #32558 Licensure and Certifuication Surveyor