Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0924082	12/13/2018
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
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 data and a lack of calibration verification (C/V) records for the Reichert Bilirubinometer (used for neonatal Bilirubin testing), and interviews with Testing Personnel (TP) #1 and the Technical Consultant, the surveyor determined the laboratory failed to perform C/V's every six months, since use of the analyzer began in June 2017 (eighteen months previously). 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 20.8 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 on page 14, "...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. There were no Reichert Unistat Bilirubinometer C/V records available for review. 4. During an interview on 12/13 /2018 at 11:20 AM, the surveyor asked TP #1 about the calibration procedure on the Bilirubinometer; TP #1 explained she calibrated with the 20.8 mg/dl calibration cuvette every six month. As the interview continued, the surveyor then asked the Technical Consultant if the laboratory had implemented a calibration verification procedure since only one calibrator was used for calibrations. The TC confirmed the laboratory had not performed a C/V since the analyzer was validated in June 2017. .
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on a review of validation documentation for the Reichert Unistat Bilirubinometer (used for neonatal Bilirubin testing), and an interview with the Technical Consultant, the surveyor determined the Laboratory Director failed to ensure his review and approval of the initial validation procedures to verify the manufacturer's performance specifications, was performed and documented before patient testing began. The findings include: 1. A review of the installation and validation records for the Reichert Unistat Bilirubinometer analyzer revealed the laboratory established precision and accuracy by running two levels of Pediatric Bilirubin QC for 15 days from 6/5 to 6/30/2017. The data was reviewed and approved by the Laboratory Director and Technical Consultant on 7/12/2017. 2. A review of the Reportable Range / Accuracy study using a five-level Verichem Bilirubin Standard Kit was performed on 6/12/2017; the data was reviewed and approved by the Laboratory Director and Technical Consultant on 6/12/2017. 3. During an interview and review of these records on 12/13/2018 at 8:40 AM, the surveyor asked the Technical Consultant about the approval of the Bilirubinometer on 6/12/2017, since the validation of the analyzer's precision was still in progress until 6/30/2017. The TC stated they had based their approval on the precision of the QC data from 6/5 thru 6/12 /2017. The surveyor then asked about the notations of "NPT" (No Patients Tested) for several of the days in June 2017, and asked if patient testing was performed on the other days. TP #1 confirmed that she had run neonatal bilirubins in June 2017. When asked if she had run any patient samples between 6/5 and 6/11/2017 (before use of the Bilirubinometer was approved by the Laboratory Director and Technical Consultant on 6/12/2017), TP #1 checked her patient log, and stated she had performed two

	patient bilirubins. Thus the above noted findings were confirmed. SURVEYOR: Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor