Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0691847	07/06/2023
Name of Provider or Supplier	**Street Address, City, State**	
East Tn Childrens Hospital Primary Care Corp	502 Winfield Dunn Parkway, Sevierville, TN	

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
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of manufacturer's instruction manual, laboratory records, and interview with the laboratory liaison, the laboratory failed to follow manufacturer's instructions for calibration in 2022 and 2023. The findings include: 1. Observation of the laboratory on July 5, 2023 at 9:10 a.m. revealed the Reichert Unistat Bilirubinometer on the counter in use for pediatric patient testing for total bilirubin. (Serial number 00690-1013). 2. Review of the manufacturer's instruction manual revealed that the Bilirubinometer is to be calibrated at least every six months, or earlier if indicated by quality control data, using stable assayed glass calibration cuvette. 3. Review of laboratory records revealed no records were present for calibration of the Bilirubinometer from July 2022 through date of survey (July 6, 2023). 4. Interview with the laboratory liaison on July 6, 2023 at 12:30 p.m. confirmed the laboratory failed to follow the manufacturer's instructions for calibration of the Bilirubinometer every six months in 2022 and 2023.