Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0684710	(X3) Date Survey Completed 04/07/2022
Name of Provider or Supplier Knoxville Pediatric Associates	**Street Address, City, State** 2201 Clinch Avenue, Knoxville, 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
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: ========== Based on the laboratory's 2022 Proficiency Testing (PT) performance summary report from the College of American Pathologisits (CAP) Proficiency testing program and interview with the Nurse Manager, the laboratory failed to review and document remedial action for Unsatisfactory hemoglobin analyte results first event 2022. Finding Include: 1. Review of the laboratory's 2022 CAP Proficiency Testing summary report for Hemoglobin analyte revealed the laboartory failed to review and document remedial action for failed hemoglobin analyte results first event 2022. 2. Interview with the Nurse Manager on April 7, 2022 at 12:30 pm confirmed the laboratory failed to review and document remedial action for failed hemoglobin analyte results PT first event 2022. ==========
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 review of the Cell-Dyn Emerald instrument operator's manual for complete blood count (CBC), CBC instrument calibration records, and interview with the Nurse Manager, the laboratory failed to follow manufacturer's requirements for CBC instrument calibration frequency in 2020. The findings include: 1. Review of the Cell-Dyn Emerald instrument operator's manual for CBC revealed that calibration is to be performed "At least every six months." 2. Review of CBC instrument calibration records revealed the calibration was not performed in 2020. 3. Interview with Nurse manager on April 7, 2022 at 12:30 pm confirmed lack of calibration performance in 2020. ==========