Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0896759	05/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
East Tn Hematology & Oncology	1021 Coolidge St Ste 3, Greeneville, 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
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 review of Quality Assurance (QA) Plan, lack of QA documentation for 2018 and 2019 and upon interview with the primary testing person and Laboratory Supervisor, determined the laboratory failed to follow QA plan for 2018 and 2019. The findings include: 1. Review of QA Plan states that monitors will be: a. Monthly Chart Audits b. Proficiency Testing Tracking Sheet c. Mainenance, Calibration and QC Tracking Sheet d. Communications, Complaints, Problems and Personnel Tracking Sheet 2. Lack of QA documentation for 2018 and 2019. 3. Interview with the primary testing person and Laboratory Supervisor at approximately 12:30 p.m. May 14, 2019 confirmed the laboratory had not been performing Quality Assurance Monitors for the last 2 years. ==========
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by:

	========== Based on review of CBC (Complete Blood Count) instrument maintenance requirements, review of maintenance logs for 2019 and interview with the primary testing person and laboratory supervisor, determined the laboratory failed to document CBC instrument maintenance since April 15th, 2019. The findings include: 1. Review of the CBC instrument maintenance requires daily, monthly and PRN (as needed) maintenance to be performed (see maintenance log attachment). 2. Review of maintenance logs for 2019 revealed maintenance had not been documented since April 15th, 2019. 3. Interview with primary testing person and laboratory supervisor at approximately 12: 30 p.m. May 14, 2019 confirmed that maintenance for the CBC instrument had not been documented since April 15th, 2019. ==========
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 review of Calibration Verification for the CBC instrument to be done every 6 months per procedure, lack of 6 month calibration verification after 8/6/18 and interview with the primary testing person, determined the laboratory failed to follow their procedure for calibration verificaton every 6 months. The findings include: 1. Review of the Calibration Verification procedure for the CBC instrument states to perform every 6 months. 2. Lack of 6 month calibration verification after 8/6/18. 3. Interview with the primary testing person at approximately 12:00 p.m. May 14, 2019 confirmed the last calibration verification for the CBC instrument was performed 9 months previously on 8/6/18, thus failing to follow procedure for performing every 6 months. ==========