Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0096510	05/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Hartford Healthcare Cancer Institute At	425 Post Rd, Ste 204, Fairfield, CT	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have a policy in place to assess the competency based on position responsibilities for laboratory personnel in the specialty of hematology. Findings include: 1. Review of the laboratory's competency records on 5/23/19 revealed the following: a. The laboratory did not have policy in place to assess the competency based on position responsibilities for the technical consultant and clinical consultant. b. Competency documentation for the above laboratory personnel was not available for 2017 and 2018. 2. Staff interview with the laboratory supervisor on 5/23/19 at 11:30 AM confirmed the above findings. 3. the laboratory performs 6,787 complete blood count tests annually.
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 record review and staff interview, the laboratory failed to perform calibration on the hematology analyzer at the required frequency. Findings include: 1. Record review of the calibration records on 5/23/19 revealed the following: a. Abbott Diagnostics Emerald Analyzer was calibrated on: 5/2/17, 9/26/17, 12/7/17, 2/23/18, 4 /19/18 and 4/19/19. b. Records of semi-annual calibration was not available for the period of April 2018 to April 2019. 2. Staff interview with the laboratory supervisor on 5/23/19 at 11:00 AM confirmed the semi-annual calibrations were not performed in a timely manner for the above indicated period. 3. The laboratory performs 6,787 complete blood count tests annually.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to evaluate testing personnel to ensure competency to perform and report accurate test results in the specialty of hematology. Findings include: 1. Record review of testing personnel (TP) competency records on 5/23/19 revealed 1 of 5 TP performing complete blood count (CBC's) was not evaluated in 2017 to assess their competency for all six required competency assessment criteria. 2. Staff interview with the laboratory supervisor 5/23 /19 at 10:00 AM confirmed the findings above. 3. The laboratory performs 6,787 CBC tests annually.