Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0096510	09/13/2023
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
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor observation, record review and staff interview, the laboratory failed to follow their policies and procedures and document corrective action when temperatures exceeded acceptable ranges in the specialty of hematology and Chemistry for the period of January 2022 through August 2023. Findings Include: 1. Record review on 09/13/2023 of the 'Fridge Min/Max temperature log' for January 2022 through August 2023 revealed the following: a. Acceptable refrigerator temperature range is 2 to 8 degrees Celsius. b. Lack of documentation of corrective action for 343 of 423 working days when the refrigerator temperature was below the acceptable range in 1a above. c. Signed as reviewed by testing personnel #1 (TP#1) monthly. 2. Record review on 09/13/2023 of the 'Room Temperature Min/Max temperature log' for January 2023 through August 2023 revealed the following: a. Acceptable room temperature range is 15 to 30 degrees Celsius. b. Lack of documentation of corrective action for 52 of 84 working days when the room temperature was above the acceptable range in 2a above. c. Signed as reviewed by TP#1 monthly. 3. Record review on 09/13/2023 of the 'Oncology Clinics-Environmental Monitoring ONC 10009' standard operating procedure revealed the

	following: a. 'Section supervisors are responsible for ensuring that environmental monitoring is being performed as required. Any monitoring data that requires corrective action must be brought immediately to the attention of the administrative director. The administrative director is responsible for instituting the appropriate corrective actions. The laboratory director will review environmental monitoring data to ensure that the appropriate conditions are being attained.' b. 'Corrective actions: if temperature exceeds acceptable limits, the building manager (or maintenance department if applicable) will be called immediately to resolve the problem.' 4. Surveyor observation on 09/13/2023 at 11:15 AM of the hematology and chemistry laboratory revealed a room temperature thermometer behind the ACE Excel chemistry analyzer. 5. Staff interview on 09/13/2023 at 11:30 AM with TP#1 verified the temperatures were out of range and documentation of corrective action was not reported.