Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0093009	(X3) Date Survey Completed 12/12/2018
Name of Provider or Supplier Hartford Healthcare Cancer Institute	**Street Address, City, State** 183 North Mountain Rd, New Britain, 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 of all laboratory personnel. Findings include: 1. Review of the laboratory's personnel competency records on 12/12/18 revealed the following: a. The laboratory did not have policy in place to assess the competency of the technical consultant and clinical consultant. b. Competency documentation for the above laboratory personnel was not available. 2. Staff interview with testing personnel #1 on 12/12/18 at 11:10 AM confirmed the laboratory did not have a policy in place to assess the competency of the above laboratory personnel and they were not assessed.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and staff interview, laboratory failed to follow established laboratory procedures in the specialty of chemistry and hematology. Findings include: 1. Record review of the in use quality control (QC) validations on 12/12/18 revealed

	that testing personnel (TP) were not following the laboratory procedure when validating new lots of QC, specifically for the following: a) Alfa Wassermann Level 1 & 2 chemistry QC lot#1213UNCM & 937UECM in 2018. b) Sysmex Level 1, 2 and 3 hematology QC lot# 82960804, 82960805 and 82960806 in 2018. 2. Record review of the laboratory's "Oncology Clinics-Quality Control Sysmex XS" and "Introduction to Quality Control Practices" procedures for new lot of QC testing on 12/12/18 revealed the supervisor will calculate the mean and standard deviation (SD), then send it the Medical Director for review and approval. Also, QC cumulative statistics report is printed containing the estimated mean, SD and % coefficient of variation (%CV) of all the QC results for each test run on each control. 3. Interview with the laboratory TP#1 on 12/12/18 at 1:30 PM confirmed TP were not following the laboratory's procedures for the above new lots of QC in 2018. 4. Record review of the Level 1 & 2 chemistry quality controls for Alkaline phosphatase (ALP) package insert revealed the stability of the QC is 3 days once reconstituted at 2-8 Celsius. 5. Staff interview with TP#1 on 12/12/18 at 12:45 PM stated the laboratory was using a 5 day expiration date for the ALP controls. 6. The laboratory performs 77,000 chemistry tests and 57,000 hematology tests annually.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure test results were accurately sent from the point of entry to the final patient test report. Findings include: 1. Review on 12/12/18 of the laboratory's quality assessment records revealed: a. Complete metabolic panel (CMP) results were scanned into the wrong patient's chart on 7/10/18 and 8/27/18. b. Corrective action to prevent recurrence was not instituted. c. The laboratory did not have a plan in place to ensure test results were accurately scanned into the correct patient's chart. 2. Staff interview with testing personnel #1 (TP1) on 12/12/18 at 11:00 AM confirmed the above findings. 3. The laboratory performs 77,000 chemistry tests annually.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by:

	Based on record review and staff interview, the laboratory failed to ensure corrective actions were effective to prevent recurrence of problems identified in post analytical systems. Findings include: 1. Review on 12/12/18 of the laboratory's quality assessment records revealed: a. Complete metabolic panel (CMP) results were scanned into the wrong patient's chart on 7/10/18 and 8/27/18. b. The documented corrective action instituted for both dates above was to make the corrections in the patient's chart. c. The laboratory failed to ensure corrective actions put in place were effective to prevent recurrence and the incident happened again. 2. Staff interview with testing personnel #1 on 12/12/18 at 11:00 AM confirmed the above findings. 3. The laboratory performs 77,000 chemistry tests annually.