Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0096510	06/10/2021
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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the proficiency testing (PT) data report (Casper Report 155 D) and PT graded results from American Association of Bioanalysts (AAB), the laboratory failed to successfully participate for the regulated analyte hematocrit. The laboratory had unsatisfactory scores for the 3rd event of 2020 and the first event of 2021. Refer to D2130
D2130	HEMATOLOGY CFR(s): 493.851(f)

	Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on record review of the Casper Report 155 D, CMS Cumulative Scores-Regulated Analytes proficiency testing (PT) scores from American Association of Bioanalysts (AAB), laboratory's investigation/corrective action documentation and staff interview with the technical consultant (TC), the laboratory failed to achieve satisfactory performance for the regulated analyte hematocrit (HCT) in the specialty of hematology. Findings include: 1. The laboratory obtained an unsatisfactory score of 60% for the HCT analyte in the third event of 2020 (Q3-2020).. 2. The laboratory obtained an unsatisfactory score of 40% for the HCT analyte in the first event of 2021 (Q1-2021). 3. Record review of the laboratory's investigation and corrective action documentation for the above unsatisfactory PT scores on 6/10/2021 revealed the lack of documentation for testing personnel (TP) retraining and reeducation. 4. Staff interview with the TC on 6/10/2021 at 11:30 AM confirmed the laboratory failed to achieve satisfactory performance for the HCT analyte in the third event of 2020 and the first event of 2021. The TC further stated records for TP retraining and reeducation were not available. 5. The laboratory performs 42,000 tests annually in the specialty of hematology.
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 of the laboratory's standard operating procedure (SOP), calibration documentation and staff interview, the laboratory failed to follow its established procedure for calibration verification. Findings include: 1. Record review on 6/10/21 of the laboratory SOP for 'Sysmex XN-330 procedure ONC-20013' for calibration verification revealed "the laboratory must verify calibration every six months or on an as-needed basis to ensure accuracy of the system." 2. Record review on 6/10/21 of the Sysmex XN-330 calibration records revealed the analyzer was calibrated on the following dates. 12/18/18 1/22/19 4/29/19 4/29/21 Calibration records were not available between 4/29/19 and 4/29/21. 3. Staff interview with the technical consultant on 6/10/21 at 12:30 PM confirmed the above findings.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on the laboratory's Quality Control (QC) record review and staff interview with

	the technical consultant (TC), the laboratory failed to maintain and review QC records to ensure accurate test results are being reported. Findings include: 1. Record review on 6/10/21 of the laboratory's QC records for the Sysmex XNL-330 (SN# 11737) hematology analyzer revealed daily QC records were not available prior to 2021 for surveyor review. 2. Staff interview with the TC on 6/10/21 at 12:30 PM confirmed that the previous management/TC kept no records of daily QC and did not document any QC review by the TC in 2020. 3. The laboratory performs 42,000 tests annually in the specialty of hematology.