Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0094414	05/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Hartford Healthcare Cancer Institute	85 Retreat Ave, Hartford, 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
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 the laboratory failed to follow written procedures for reporting analyzer flagged complete blood count (CBC) results. Findings include: 1. Record review on 5/23/19 of the laboratory's procedure "Doc# ONC-20003: Results review and flagged results on the Sysmex XP-300" revealed: a. CBC results flagged by the Sysmex analyzer are required to be repeated. b. If the flag remains in the repeat analysis the result(s) need to be reported with a flag comment to alert the ordering physicians that the results need to be interpreted with caution. 2. Record review of the laboratory's corrective action log on 5/23/19 revealed the following samples with analyzer flags for platelets were reported without flag comment as stated in the above procedure. a. 100065395274 performed on 12/4/18. b. 100065127460 performed on 11/26/18. c. 100064233091 performed on 11/9/18. 3. Staff interview with the technical consultant (TC) on 5/23/19 at 11.45 AM confirmed the above findings. The TC further stated it is an ongoing issue and needs staff retraining. 4. The laboratory performs 90,000 tests annually in the specialty of hematology.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results

	within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to follow manufacturer's instructions when reporting test results flagged by the analyzer in the specialty of hematology. Findings include: 1. Record review on 5/23/19 of the Sysmex investigative report dated 1/18/19 for a discrepant platelet (PLT) result revealed: a. " SID 100065127460 was analyzed on XP-300 S/N B1751 on November 26, 2018 at 11:26. The analyzer generated a platelet (PLT) result of 36*x10^3u/L. The result was flagged with "PU". b. "An erroneous high PLT was reported for sample ID number 100065127460. No corrected report was issued. The nurse reported the patient would not have received radiation if PLT count was 5x10^3/uL." c. "Sysmex XP-300 instructions for use (section 8.2) - An asterisk {*} indicates the data is unreliable. All analyses generated PLT results with an asterisk, indicating the need for further review of the sample prior to resulting." d. "Section 8.3- Histogram flags, displays the various flags associated with histograms. One possible cause of the histogram flag "PU" is the presence of fragmented RBC's. A manual PLT estimate is to be performed and the smear checked." e. The above sample was sent to a reference laboratory where a PLT of 5x10^3/uL was obtained on repeat analysis. It was determined that the laboratory reports flagged test result(s) and are not following the above recommendation from the manufacturer. 2. Staff interview with the technical consultant on 5/23/19 at 10:30 AM confirmed the above findings. The above findings were discussed with the laboratory director on 5/23/19 at 1:15 PM. 3. The laboratory performs 90,000 tests annually.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to document ordering physician notification when critical values were obtained. Findings include: 1. Record review on 5/23/19 of the following patient reports revealed the testing personnel did not notify and/or document the ordering physician when critical values were obtained. a. MRN# 1001729841 with critical platelet count (PLT) and absolute neutrophil count (ANC). b. MRN# 2001316965 with critical white blood cell count (WBC). c. MRN# 2002987838 with critical hemoglobin. d. MRN# 1000656861 with critical PLT. e. MRN# 1001729841 with critical WBC, PLT and ANC.. 2. Staff interview with the technical consultant (TC) on 5/23/19 at 11:30 AM confirmed the above findings. The TC further stated that he/she is monitoring the delinquent practice. 3. The laboratory performs 90,000 tests annually in the specialty of hematology.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if

	applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to issue corrected report when originally reported results were changed. Findings include: 1. Record review on 5/23/19 of the following patient sample reports revealed a corrected report was not issued when results were corrected due to repeat analysis at a reference laboratory. SID# Analyte Original result Corrected result 100065395274 PLT 46 11 100065127460 PLT 20 5 100064053571 PLT 34 5 100065541998 PLT 34 12 2. Staff interview with the technical consultant (TC) on 5/23/19 confirmed the above findings. The TC further stated the laboratory does not usually issue corrected report when reference laboratory results are different from the original results.