Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0681236	08/01/2019
Name of Provider or Supplier	**Street Address, City, State**	
Hartford Healthcare Cancer Institute	5 Dayton Rd, Ste 205, Waterford, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to provide a complete procedure manual which includes all three phases (pre-analytical, analytical and post-analytical) of testing in the specialty of chemistry. Findings include: 1. Record review on 8/1/19 of the routine chemistry procedure manual for Envoy 500 (S /N# 48142382) chemistry analyzer revealed the lack of the following: a. Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and criteria for specimen acceptability and rejection. b. Instrument maintenance requirements. c. Control procedures. d. Calibration

	verification procedures and its frequency. d. Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. e. Procedures for reagent lot number changes. f. The protocol for reporting critical, panic, or alert test result values. g. Reportable ranges. h. Reporting of test results. The above procedure manual only contained reagent package inserts. 2. Staff interview with the laboratory supervisor on 8/1/19 at 1:00 PM confirmed the above findings. 3. The laboratory performs 37,400 tests annually in the specialty of chemistry.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer before testing patient samples. Findings include: 1. Record review on 8/1/19 of the laboratory's validation records for Sysmex XP-300 (S/N# B3941) hematology analyzer revealed the values obtained from a reportable range study indicated hemoglobin (HGB) range was established from 0.0 through 20.9 g/dL. 2. Record review on 8/1/19 of an analyzer printout dated 1/28/19 using a spiked sample revealed the highest HGB value obtained by the same analyzer was 23.8 g/dL. 3. Record review on 8/1/19 of the laboratory's hematology procedure manual (Doc# ONC-20001) revealed the HGB reportable range was listed as 0.1 through 25.0 g/dL as supplied by the manufacturer. 4. The above ranges were approved by the laboratory director on 2/8/19. 5. Staff interview with the laboratory supervisor on 8/1/19 at 10:30 AM confirmed the above findings. 6. The laboratory performs 25,200 hematology tests annually.