Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0994636	05/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Oncology Hematology Care Of Connecticut	849 Boston Post Road, Suite 100, Milford, 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 its established procedure manual in the specialty of Hematology. Findings include: 1. Record review on 5/10/22 of the laboratory's procedure manual for calibration verification revealed Hematology analyzer calibrations are to be performed twice annually. 2. Record review on 5/10/22 of the Medonics M series hematology analyzer calibration log revealed the lack of documentation of semiannual calibration for the second half of the year 2020. 3. Staff interview with the technical consultant and the laboratory director on 5/10/22 at 1245 PM confirmed the above findings. 4. The laboratory performs 42,000 hematology tests annually.
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, surveyor observation and staff interview, the laboratory failed to provide a step-by-step procedure manual in the specialty of Hematology. Findings include: 1. Record review on 5/10/22 of the laboratory's procedure manual for complete blood count (CBC) test revealed the lack of the following. a. Daily quality control (QC) acceptable criteria and procedures to follow when QC results fall outside the acceptable limits. b. Daily, weekly, and monthly maintenances to be performed for the CBC analyzer. c. CBC critical value policy. d. Normal reference ranges for CBC. 2. Surveyor observation on 5/10/22 at 10:00 AM of the CBC procedure manual revealed the following: a. An incorrect CBC analyzer (Cell-Dyn) was listed in the procedure manual. The laboratory uses a different CBC analyzer (Medonics M series) to test patient samples. b. Listed as blood smears are being prepared at the laboratory for smear review. c. Listed as erythrocytic sedimentation rate (ESR) is being performed at the laboratory. 3. Staff interview the technical consultant (TC) and the laboratory director on 5/10/22 at 1:30 PM confirmed the above findings. The TC further stated that blood smears and ESR are send out tests and not being performed onsite.