Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2119650	04/09/2019
Name of Provider or Supplier	**Street Address, City, State**	
Maryland Oncology Hematology, Pa	7704 Matapeake Business Drive, Suite 200, Brandywine, MD	

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 interview with the technical consultant, the hematology laboratory written procedures to perform automated complete blood counts did not state the number of quality control reagents used by the laboratory and when controls are tested. Findings: 1. The laboratory uses an automated analyzer to perform complete blood counts on patient specimens; 2. During interview with the technical consultant on the day of survey, the technical consultant stated that trilevel hematology quality control reagent is listed in the supply/reagent list for the test

	procedure; and 2. The quality control procedure in the laboratory's written procedure for automated hematology testing did not state if one, two or three levels of the trivalent control reagent were tested and how often the control(s) are tested.