Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2137901	07/21/2022
Name of Provider or Supplier	**Street Address, City, State**	
Potomac Oncology And Hematology	6000 Executive Blvd Suite 501, Rockville, 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 review of the new procedure manual and interview with the testing personnel (TP), the laboratory failed to ensure that the generic procedure with "fill in the blanks" instructions were completed. Findings: 1. The TP provided the survey with the new procedure manual for the hematology analyzer. 2. The laboratory purchased and validated a new hematology analyzer in February 2020. The new binder included the validation documents along with the CLIA compliance policies and procedures. The laboratory is required to "fill in the blanks" with their specific instruction where needed. None of the "fill in the blanks" had been completed in the

	new policy and procedure manual. 3. During the survey on 07/21/2022 at 10:45 AM, the TP confirmed that the new policy and procedure manual did not contain all the required "fill in the blanks" written instructions for the testing personnel to follow.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the annual evaluations and interview with the testing personnel (TP), the laboratory director acting as the technical consultant failed to ensure that all testing personnel received an annual competency review as required by the procedure manual. Findings: 1. The laboratory currently has four TP persons listed on the "Laboratory Personnel Report (CLIA) (CMS-209)." The laboratory director is acting as the technical consultant. 2. The TP evaluation records for 2020, 2021 and 2022 were reviewed. One TP had their last evaluation performed on 02/09/2021. The TP was missing their annual evaluation for 2022. Two TP had their last annual evaluation performed on 02/26/2020 and 08/19/2020. One was missing their annual evaluation for 2021 and 2022 and the other was missing their evaluation for 2021. 3. During the survey on 07/21/2022 at 10:45 AM, the TP confirmed that the annual evaluations for 2021 and 2022 were not performed by the technical consultant as required.