Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2137901	12/03/2019
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: I. Based on review of the procedure manual and interview with the testing personnel, the laboratory's policies and procedures did not reflect the activities that the testing personnel were actually performing. Findings: 1. The testing personnel stated that when they switch to a new lot of hematology quality control (QC) materials they store each of the product inserts along with the printed Levy-Jennings. They document when ever they open a new set of the QC materials on the maintenance worksheet and on daily QC instrument printouts. The policy and procedure manual was reviewed and these instructions were not present. 2. The testing personnel stated that when ever an

	abnormal patient is repeated the doctor reviews both results, selects one to be scanned into the computer, and then the two results are stapled together and stored with the patient results for that day. The policy and procedure manual was reviewed and these instructions were not present. 3. During the survey on 12/04/19 at 2:30 PM the testing personnel confirmed that the policy and procedures did not include instructions for all laboratory activities. II. Based on review of the daily patient log book, policy and procedure manuals, and interview with the testing personnel, the laboratory's procedure manual did not include an interpretation of the abbreviations used when documenting information on the daily patient log. Findings: 1. The laboratory's daily patient log book included abbreviations such as "RR", "self", "port", "IV" and "biotech." 2. Neither the worksheet nor the policy and procedure manual identified the meaning of the abbreviations used on the patient log. 3. During the survey on 12/04 /19 at 2:30 PM the testing personnel confirmed that the policy and procedures and daily patient log did not include the definition of the abbreviations used on the daily patient log book.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and interview with the testing personnel, the laboratory did not ensure that the the updated procedures reflected the date the old procedures were discontinued and when they new ones were put into use. Findings: 1. Review of the calibrator preparation instructions in the laboratory procedure manual on pages 3-5 through 3-8 showed that the word "S-CAL" had been covered with white out and "CDS" written in it's place. Also "3PD" was written over the identity of the cell controls. The procedure failed to identify when the old calibrator and controls were discontinued and when the new ones were put into use. 2. Review of the laboratory procedure manual showed that on 08/01/19 new critical values had been listed in the procedure manual. The changes had not been approved (initialed) by the laboratory director. 3. During the survey at on 12/03/19 at 2:30 PM the testing person confirmed that the laboratory procedure manual did not identify when the old calibrator and controls were discontinued, when the new ones were put into use, and that the laboratory director did not approved changes to the critical values.
D6022	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 the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the office procedure manual, monthly Levy-Jennings (L-J) graphs,

	and interview with the testing personnel, the laboratory director did not ensure that the maintenance procedures in the office procedure manual were being followed each month of testing. Findings: 1. The "Maintenance Procedures" in the office procedure manual states "When controls with a new lot are used for the first time, all existing QA of the prior lot should be printed off as well as the Lenning-Jennings graphs." (Please note typo in procedure manual) 2. The L-J graphs for March 2018 through November 2019 were reviewed. The L-J graphs for the months of March 2018 through April 2019 were not available. 3. The quality control (QC) printouts that were available from March 2018 through November 2018 showed 9 months worth of QC data with the expiration date of the QC materials used in November 2019. The QC materials are good for 2-3 months, therefore, the QC data from March 2018 did not have the correct expiration date on the most recent printout. 4. The monthly quality assessment (QA) reviews showed that the QC had been reviewed and found acceptable for the months of May 2018 through April 2019 but there were no L-J graphs available showing what had been reviewed and found acceptable. 5. The laboratory director did not ensure that all the QA and QC documentation was maintained and available for the required two years. 6. During the survey on 12/04/19 at 2:30 PM the testing personnel confirmed that the QA and QC data was not available at the time of the survey.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of the procedure manuals and interview with the testing personnel, the laboratory director did not ensure that all policies and procedures followed in the laboratory were approved (signed and dated). Findings: 1. Review of the laboratory and office procedure manuals showed that the office procedure manual, that included specific maintenance and proficiency testing procedures, was not approved (signed and dated) by the laboratory director. 2. During the survey at on 12/03/19 at 2:30 PM the testing person confirmed that the office procedure manual was not signed and dated by the laboratory director.