

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2137901	(X3) Date Survey Completed 08/27/2018
Name of Provider or Supplier Potomac Oncology And Hematology	Street Address, City, State 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	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the supervisor, the laboratory's "Reporting Protocol" did not reflect the activities that the testing personnel were actually performing. Findings: 1. The "Reporting Protocol" procedure states "prior to visiting each Patient in room or chemotherapy, Dr. Xu is handed report or checks report himself in "CBC results (today)" folder." 2. According to the testing personnel there are many other activities that performed that are not listed in the procedure. The testing personnel also enter the accession number into the hematology analyzer, write the patients name on the printout, scan the report and attach to the</p>

	<p>patients electronic medical record and store the original in a file folder. 3. During the survey on 08/27/18 at 12:00 PM the laboratory director confirmed that the policy and procedure manual did not contain all the required written instructions for the laboratory staff.</p>
<p>D5417</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on review of the hematology quality control (QC) records and interview with the lead testing person and laboratory director, the laboratory did not ensure that hematology QC materials were not used after their expiration date. Findings: 1. The QC records for the hematology analyzer for 2018 were reviewed. The hematology QC records show that lot #31803 expired on 07/23/18. The QC records show that the expired QC materials were tested on 07/25, 07/27, 07/28 and 08/01/18 along with approximately 48 patients. 2. During the survey on 08/27/18 at 12:00 PM the the lead testing person and laboratory director confirmed that the laboratory had used expiration QC materials when testing and reporting patient test results.</p>
<p>D5805</p>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on review of patients final reports and interview with the supervisor, the laboratory did not ensure that the final test report listed the address of the laboratory performing the tests. Findings: 1. During the survey patient charts were pulled to review the final report with the patients test results. The final reports that were reviewed did not include the address of the laboratory performing the tests; 2. During the survey on 08/27/18 at 12:00 PM the laboratory supervisor confirmed that the final reports did not include the address of the laboratory performing the tests.</p>