Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2230264	01/25/2024
Name of Provider or Supplier	**Street Address, City, State**	
Potomac Oncology And Hematology	12800 Middlebrook Rd Suite 430, Germantown, 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
D2005	ENROLLMENT CFR(s): 493.801(a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. This STANDARD is not met as evidenced by: Based on record review, the laboratory did not request that the proficiency test provider (API) report proficiency test scores for testing performed on the hematology analyzer to CMS (Centers for Medicare & Medicaid Services). Findings: 1. The Proficiency test results for the hematology analyzer were not reported on the CASPER report 96D (CLIA application and survey summary) for the laboratory. 2. The proficiency test providers reports in 2023, to the laboratory, evaluating the laboratorys performance for the hematology analyzer did not state that the proficiency test scores (performance) were reported to CMS. 3. The API website for reporting laboratory proficiency test evaluations does not show that the CLIA number associated with the Germantown office was enrolled for proficiemcy testing.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of proficiency testing records, and interview, the laboratory did not

	rotate proficiency testing among all testing staff. Findings: 1. At the time of the survey, the laboratory had at least two staff members that should have shared or rotated duties for testing proficiency test samples and reporting the results to the proficiency test provider for evaluation of performance, but only one testing person performed the proficiency testing for in 2023. 2. This was confirmed during interview with testing person #1 on the afternoon of the day of survey.
D2011	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample (s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program. This STANDARD is not met as evidenced by: Based on review of written procedures, the hematology laboratory (CBC testing on the hematology analyzer) did not have written procedures to ensure proficiency test results were not compared between the Rockville office laboratory and the Germantown office laboratory prior to reporting results to the proficiency test provider for evaluation. Findings: 1. Proficiency test providers mail a set of unknown samples to laboratories for testing, the providers receive the test results and evaluate the laboratories accuracy. A proficiency test event occurs each time a shipment of unknown samples is received by the laboratory. 2. Testing staff rotate between the Rockville and Germantown office. For each proficiency test event, both offices receive the same proficiency testing samples from the same proficiency testing provider as each duplicate set of samples arrive in two separate boxes at the Rockville office before having one box of samples taken to the Germantown office for testing. 3. There is no written procedure to ensure that the results obtained from the two offices are not compared between the two laboratories prior to reporting to the proficiency test provider for scoring or evaluating performance, and that the same person does not perform the proficiency testing at both offices for the same test event. 4. If the laboratories cannot ensure that different people perform the proficiency testing for the Germantown and Rockville laboratories for a single proficiency test event, then the laboratory will need to use a different proficiency test provider for each location.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) 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. This STANDARD is not met as evidenced by: Based on interview and review of the laboratory reagent log, the laboratory did not maintain a record of the manufacturer's name, lot number and expiration date of the hematology reagent pack used for hematology testing on the analyzer to ensure they

	were not used past expiration. Findings: 1. The last recorded reagent on the laboratory log was on May 14, 2021. 2, This was confirmed during interview with testing person #1 on the afternoon of the day of survey.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on record review, the laboratory staff did not document corrective actions taken daily, when hematology (CBC analyzer) quality control testing failed to meet the laboratory's criteria for acceptability. Findings: 1. Page 21 of the laboratory quality control written procedure states that failure to recover control values within the expected limits are investigated and quality control results must be in expected ranges before reporting patient results, if the results are not acceptable then repeat, if the repeat test results are still unacceptable then open a new vial, if the results from the newly opened vial are still unacceptable, then call tech support for assistance. If any of these corrective actions are taken then they must be documented daily. 2. On the following days there were quality control failures, but the laboratory did not have a daily corrective action log to report the failures, and did not state the actions taken by staff to correct failures (as stated in the laboratory quality control procedure) and the laboratory did not document the outcome of the staffs corrective actions to ensure the laboratory followed the written quality control procedure: a) On August 4, 2023 the control results for the low red blood cell count (rbc) count was 2.66 (the acceptable range was 2.14-2.64), and the normal rbc count was 4.42 (the acceptable range was 3.83-4.33). Two of the three rbc controls (low and normal) failed to meet the laboratory's criteria for acceptability and patient testing was performed. b) On August 18, 2023 the control results for the low rbc count was 2.88 (the acceptable range was 2.14-2.64), and the high rbc count was 5.69 (the acceptable range was 4.97-5.57). Two of the three rbc control results (low and high) failed to meet the laboratory's criteria for acceptability and patient testing was performed. 3. Testing staff did not investigate these failures, and take and document corrective actions as stated in the written procedure on the days they occurred to correct the problem immediately.