| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 21D2137901 | 02/09/2024 |
| **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 |
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| **D2011** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(3)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>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 |

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| | 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. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview, the laboratory did not validate the current hematology CBC analyzer for accuracy. Findings: 1. In November 2023, the laboratory replaced the hematology (CBC) analyzer with another analyzer. 2. The validation studies did not include the testing data and summary used to determine and evaluate the accuracy of the current hematology analyzer. 3. This was confirmed during interview with testing person #1 at noon on the day of survey. |
| **D5783** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(2)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review, 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. The laboratory did not document daily corrective actions when quality control results for hematology testing on the CBC analyzer failed to meet the laboratory's criteria for acceptability, but instead performed a monthly review of hematology quality control results to identify quality control failures and whether or not corrective actions were taken. This review was conducted at the end of the month. 2. The laboratory did not have a daily record of hematology control results that failed and the corrective actions that were taken to get the quality control checks to pass and the final outcome (whether or not the control results passed and, if necessary, what the laboratory did if quality control did not pass that day. 3. This was confirmed during interview with testing person #1, at noon of the day of survey. |