

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 21D0210246	<b>(X3) Date Survey Completed</b> 05/25/2021
<b>Name of Provider or Supplier</b> Maryland Oncology Hematology, Pa	<b>Street Address, City, State</b> 8926 Woodyard Rd # 101, Clinton, MD	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>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</p> <p>This STANDARD is not met as evidenced by: Based on remote record review and phone interview with the testing person (TP), the laboratory failed to log proficiency testing (PT) samples for blood cell identification with the laboratory's regular patient workload. Findings: 1. The laboratory performs peripheral blood smears. Each slide that is prepared and stained is recorded on a monthly slide staining quality control log which contains columns labeled "Date of Request", "Patient Name", "Patient MR Number", "Requesting Physician's Name", "Date Slide Stained", "Date Slide Reviewed by Physician", and "Physician's Request and Result/Interpretation Documented in EMR." 2. According to the TP, the laboratory personnel prepare and stain the slides and the physicians evaluate the slides and interpret the results. The monthly log is the only record that the slide has been prepared and evaluated. 3. The laboratory participates in hematology PT for "Blood Cell Identification" which consists of 6 images of peripheral blood smears with arrows pointing to the cells to be identified. 4. During the phone interview on 05/25 /2021 at 12:30 PM, the TP confirmed that the PT "Blood Cell Identification" specimens are not recorded on the monthly slide staining quality control log, as being read by the physicians, with the laboratory's regular patient workload.</p>
<b>D6128</b>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually</p>

after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on remote record review and phone interview with the technical supervisor (TS) and testing person (TP), the TS failed to evaluate and document the performance of high complexity testing personnel annually. Findings: 1. The laboratory performs peripheral blood smears which are prepared by the testing personnel and read by the physicians at the practice. 2. The physicians participate in hematology proficiency testing (PT) for "Blood Cell Identification" which consists of 6 images of peripheral blood smears to be interpreted and reported. 3. Though the physicians rotate the PT specimens and sign the PT attestation statements, there is no annual evaluation performed and documented by the TS for the physicians performing high complexity testing. 4. During the phone interview on 05/28/2021 at 12:30 PM, the TP and TS confirmed that there is no documentation of annual evaluations performed for the physicians who are reading and interpreting the peripheral blood smears.