

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0210899	(X3) Date Survey Completed 07/09/2021
Name of Provider or Supplier Maryland Oncology Hematology-Lanham	Street Address, City, State 8116 Good Luck Road Suite 100, Lanham, 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 remote record review and interview with the testing person (TP), the laboratory's procedure manual did not define what was to be documented in the "Miscellaneous" section of the "Maryland Oncology Hematology Bench Log" worksheet. Findings: 1. The "Miscellaneous" section of the "Maryland Oncology Hematology Bench Log" worksheet was reviewed. The documentation included patient names, an identification number and a test result. 2. According to the TP, panic test results are received from the reference laboratory, documented on the "Miscellaneous" section of the worksheet are then being reported to the patients</p>

physician. The worksheet did not identify which laboratory the results were from and whether the results were given to the appropriate physician. 3. During the phone interview on 07/09/2021 at 12:00 PM, the TP confirmed that the procedure manual did not define what was to be documented in the "Miscellaneous" section of the "Maryland Oncology Hematology Bench Log" worksheet.

D5805

TEST REPORT
CFR(s): 493.1291(c)

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.

This STANDARD is not met as evidenced by:

Based on remote record review and interview with the testing person (TP), the laboratory did not ensure that the final test report, when reprinted for review included the address of the laboratory listed on the CLIA certificate being surveyed. Findings: 1. The laboratory that was being surveyed is a satellite office that uses the same laboratory information system (LIS) that several other offices in the practice use. 2. As part of the remote survey process the laboratory provided two redacted patient reports that were printed at a different satellite office. When the reports were reviewed it was determined that both final reports included the address of the satellite office where they were printed and not the address of the laboratory where the testing was actually performed. 3. During the phone interview on 07/09/2021 at 12:00 PM, the TP confirmed that the LIS did not ensure that the correct address of the testing laboratory was included on the final report.

D6072

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1425(b)(3)

Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:

Based on remote record review and phone interview with the testing person (TP), the testing person did not ensure that the location at which the testing was being performed was circled on the generic worksheets. Findings: 1. Worksheets from January 2019 through April 2019 and November 2020 through February 2021 were reviewed. 2. The "Maryland Oncology Hematology [MOH] Bench Log" lists three different addresses for MOH at the top of the worksheet. None of the worksheets from January 2019 through April 2019 and November 2020 through February 2021 included a circle around the appropriate MOH address indicating the MOH location at which the daily quality assurance (QA) activities were being documented. 3. The "Maryland Oncology Hematology Temperature Log" and "Maryland Oncology Hematology Daily Maintenance" worksheets from January 2019 through April 2019

did not include a circle around the MOH address of the laboratory where the temperature was being recorded and the daily maintenance was being performed. 4. During the phone interview on 07/09/2021 at 11:30 AM, the TP confirmed that the worksheets failed to include the identity of the MOH facility where the bench QA, temperature, and daily maintenance logs were being performed.

D6125

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:
Based on remote record review of the competency documentation, proficiency testing (PT) results and interview with the technical supervisor (TS), the TS did not ensure that written policies and procedures included the evaluation of the competency of the high complexity testing personnel who interpreted the peripheral blood smears. Findings: 1. The "Laboratory Personnel Report (CLIA)" (CMS-209) listed five testing personnel who performed high complexity testing. 2. The annual evaluations for 2019 and 2020 were reviewed. None of the evaluations included the high complexity TP. 3. The PT results for 2020 were reviewed. The attestation worksheets included illegible initials/signature of the high complexity TP who performed the interpretation of the kodachromes. 4. During the phone interview on 07/09/2021 at 12:00 PM, the TS confirmed that there were no written procedures defining how the high complexity TP would be evaluated; how the PT samples would be distributed among the high complexity TP; how they would be evaluated; corrective actions to be taken when there were failures; and where the records would be stored.