

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2300987	(X3) Date Survey Completed 05/09/2025
Name of Provider or Supplier Maryland Oncology Hematology - Largo	Street Address, City, State 9333 Healthcare Way, 4th Floor, Largo, 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 standard operating procedure manual (SOPM) and interview with the technical supervisor (TS), the laboratory's SOPM did not include the procedure for staining and evaluating blood smear slides. Findings: 1. The laboratory sometimes evaluated abnormal blood cells by staining and reviewing blood smears under a microscope. 2. During the initial survey on 05/09/2025 at 11:45 AM, the TS confirmed that an approved procedure for staining and evaluating blood smears was not included in the SOPM.</p>

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(1)

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.

This STANDARD is not met as evidenced by:

Based on review of verification records and interview with the technical supervisor (TS), the laboratory failed to document that the hematology test system obtained performance specifications comparable to those established by the manufacturer for accuracy, precision, and reportable range for test results. Findings: 1. The manufacturer performed the installation and verification for the hematology analyzer. 2. Records from the installation stated "Analyzed all levels of the customer's QC [quality control]. All parameters of all levels were within manufacturer's assay and within the customer's established range. Analyzer is ready to run samples in customer mode." The same report included a chart with data from a precision experiment on sample "CL-41342101" and the binder included instrument printouts for three levels of QC and sample "CL-4142101." 3. The records did not include a procedure that stated how the accuracy, precision, and reportable range studies were performed and that defined the acceptability criteria for each. 4. There was no additional documentation showing that the verification study results were comparable to the manufacturer's established specifications for accuracy, precision, and reportable range. 5. During the exit interview on 05/09/2025 at 12:30 PM, the TS confirmed that there was no additional documentation defining acceptability criteria and showing that the accuracy, precision, and reportable range for the hematology analyzer met the manufacturer's established specifications.