

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0677093	(X3) Date Survey Completed 08/12/2025
Name of Provider or Supplier Cliffside Medical Emergimed Laboratory	Street Address, City, State 663 Palisade Ave, Cliffside Park, NJ	
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>(b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 surveyor review of the Procedure Manual (PM) and interview with the Technical Consultant (TC), the PM lacked Reference Intervals (RI) for Hematology tests performed on the Medonic M Series analyzer from 1/1/23 to 8/12/25. The findings include: 1. The PM lacked normal patient RI and the source for complete blood count tests performed on the Medonic M series analyzer. 2. The TC confirmed on 8/12/25 at 11:00 am, the PM lacked RI and a source for complete blood count tests performed on the Medonic M series analyzer.</p>

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

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

(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 surveyor review of Performance Specification (PS) records and interview with the Technical Consultant (TC), the laboratory failed to ensure that all PS records were adequate for Hematology tests performed on the Medonic M Series from 1/1/23 to 8/12/25. The findings include: 1. The laboratory failed to perform a reference interval verification. 2. The TC confirmed on 8/12/25 at 11:30 am, the laboratory failed to ensure that all PS records were adequate.

D5807

TEST REPORT

CFR(s): 493.1291(d)

(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on the surveyor review of the Electronic Medical Record Test Reports (EMRTR), Medonic Test Records (MTR), Procedure Manual (PM), and interview with the Technical Consultant (TC), the laboratory failed to have accurate Reference Intervals (RI) for Hematology tests performed on the Medonic M Series analyzer from 1/1/23 to 8/12/25. The findings include: 1. Surveyor review of EMRTR and MTR and revealed that both reports had different RI for five out of five patients. 2. The following analytes did not have RI that matched on both the EMRTR and MTR: Red Blood Cell, Granulocytes, Granulocyte percentage, Hemoglobin, Hematocrit, Mean Corpuscular Volume, Mean Corpuscular Hemoglobin, Mean Corpuscular Hemoglobin Concentration, Lymphocytes, Lymphocytes Percentage, Red Cell Distribution Width and Mean Platelet Volume. 3. The TC confirmed on 8/12/25 at 11:20 am, the laboratory did not have accurate RI's.