Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0319163	(X3) Date Survey Completed 05/24/2022
Name of Provider or Supplier Mea Medical Clinic Laurel	**Street Address, City, State** 1515 Jefferson St, Laurel, MS	

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	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, the Medonic M-Series Hematology Analyzer Procedure Manual, and the Medonic M-Series User Manual, the laboratory failed to establish a written procedure for the performance of complete blood count (CBC) testing and interpretation of results when patient results are flagged with white blood count (WBC) differential abnormality flags by the Medonic M-Series hematology analyzer. Findings include: The Medonic M-Series Hematology Analyzer Procedure Manual states, "The following flags cover abnormalities in the WBC differential and indicate a possible problem with the accuracy of the results:

	BD, NM, OM, TM. Refer to the Medonic M-Series User's Manual for detailed information regarding the messages, their descriptions, and suggested actions for resolving them." The Medonic M-Series User's Manual states to follow the laboratory's protocol for verification of results with these flags. Review of the laboratory procedure manual revealed no written procedure for the performance of CBC testing and interpretation of results when patient results are flagged with the WBC differential flags - BD, NM, OM, TM.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the Medonic M-Series Hematology Analyzer Procedure Manual, used as the procedures for performing complete blood count (CBC) testing, and lack of documentation of review, the Medonic M-Series Hematology Analyzer Procedure Manual has not been approved and signed by the laboratory director, since CBC testing with the Medonic hematology analyzer began on 9/15/20. Findings include: Review of the Medonic M-Series Hematology Analyzer Procedure Manual revealed no documentation that it was approved and signed by the laboratory director. The laboratory began patient CBC testing with the Medonic M-Series hematology analyzer on 9/15/20.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of the verification of performance specifications for the CDS Medonic hematology analyzer performed at installation on 9/14/20 and lack of documentation of review of these records, the technical consultant failed to ensure that the verification procedures used were adequate to determine the accuracy, precision, and reportable range of the CDS Medonic hematology analyzer, which was put in use for patient complete blood count (CBC) testing on 9/15/20. Findings include: Review of the verification of performance specifications for the CDS Medonic hematology analyzer revealed a reportable range study, which also verified accuracy and precision, was performed on 9/14/20. However, there was no documentation of review of these records by the technical consultant to ensure these verification procedures were adequate to determine the accuracy, precision, and reportable range of the CDS Medonic hematology analyzer before the system was put in use for patient CBC testing on 9/15/20.