Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0688168	09/29/2022
Name of Provider or Supplier	**Street Address, City, State**	
Hackleburg Medical Clinic	34867 Hwy 43, Hackleburg, AL	

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
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the Medonic M Series Hematology records, and an interview with Testing Personnel #1, the laboratory failed to ensure daily maintenance was performed and documented from the date of the previous survey (4/28/2021) to the date of the current survey (9/29/2022). The findings include: 1. A review of the Medonic M Series records revealed the laboratory documented the 2021 and 2022 monthly and six-month maintenance on "Maintenance and Calibration Schedule" forms. There was no documentation of daily maintenance. 2. A review of the Maintenance section in the Medonic M Series Users Manual revealed instructions for daily maintenance which included cleaning the Open Tube and Pre-dilute probes with an alcohol wipe; in addition the laboratory should remove any blood or salt crystals from around the probes, rinse cup, and cap piercer. 3. During an interview with Testing Personnel #1 on 9/29/2022 at 3:05 PM, the surveyor reviewed the "Daily Quality Control and Maintenance" log available in the Medonic M Series Users Manual. There was also space available for recording the lot numbers of Clot Prevention and Cleaning kits used for the monthly and six-month maintenance. The surveyor explained the laboratory should document the lot numbers in case there is a reagent problem or a recall. Testing Personnel #1 stated she never knew about this daily maintenance sheet. .
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)

	(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the Medonic M Series Hematology Quality Control (QC) records, and interviews with Testing Personnel (TP) #1 and #3, the laboratory failed to ensure data from each day of QC was included on Levy Jennings (L-J) charts or the Interlaboratory Quality Assurance Program (IQAP) reports to track for shifts and trends over time. The laboratory failed to include 43 days of QC data from August 2021 through August 2022. The findings include: 1. A review of the Medonic M Series Hematology QC records revealed the laboratory printed cumulative monthly reports with the daily QC data, and the L-J charts attached. However, the surveyor noted five months with a total of 43 days of missing QC results, as follows: A) 8/2--8/11/2021 B) 1/28--2/7/2022 C) 3/1--3/9/2022 D) 5/2--5/16/2022 E) 8/1--8/12/2022 The surveyor confirmed QC was performed on the above date by reviewing the daily instrument printouts. 2. A further review of the CDS (Clinical Diagnostic Solution) IQAP data revealed QC from the above dates was not included in the laboratory's monthly reports. 3. During an interview on 9/29/2022 at 2:45 PM, the surveyor asked TP #1 and #3 about the the process for printing the cumulative monthly QC, and submitting the data to CDS for inclusion in the IQAP statistics. TP #1 explained she had noticed whenever she implemented a new lot number of QC in the middle of the month, then only the data for the current lot number would print at the end of the month. As an example, the only data available for August 2022 was the 8/15--8/31/2022 QC. TP #3 also confirmed this was the only data available to submit to the CDS IQAP website. 4. As the interview continued on 9/29/2022 at 3:05 PM, the surveyor explained it was possible data from the old lot number of QC was deleted whenever a new lot number was implemented. However, the laboratory should confer with the Medonic Tech Support and implement a mechanism to ensure all the QC data was documented and included in the I-J charts and the IQAP evaluation. .
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of Medonic M Series Hematology Quality Control (QC), reviews of patient test logs and charts, and an interview with Testing Personnel #1, the laboratory failed to ensure QC performed in the MC (Microcontainer) mode was within acceptable ranges before patient CBC's (Complete Blood Counts) were run. The surveyor noted two to three levels of QC were unacceptable on nine days of

	patient testing in June and July 2022. The findings include: 1. A review of Medonic M Series records revealed testing personnel ran three levels of QC in the CP/OT (Cap Piercing/Open Tube) mode and the MC mode each day of patient testing. Only the individual instrument printouts displayed the mode in which a QC or patient specimen was performed. 2. A review of the individual instrument QC printouts from June and July 2022 revealed nine days when two to three levels of QC run in the MC mode were unacceptable and 51 patient CBC's were performed (according to the patient test logs), as follows: A) 6/23/2021--Ten patient CBC's B) 7/02/2021--Four patient CBC's C) 7/09/2021--One patient CBC D) 7/12/2021--Ten patient CBC's E) 7/14/2021--Eight patient CBC's F) 7/15/2021--Six patient CBC's G) 7/16/2021--Two patient CBC's H) 7/23/2021--One patient CBC I) 7/26/2021-Nine patient CBC's 3. A review of the laboratory processes for test reporting revealed the facility utilized the instrument printout as the patient report, and included these in each patient's paper chart. The facility was unable to pull 51 patient charts on the day of the survey to determine how many patient CBC's were performed in the MC mode. 4. During an interview on 9/29/2021 at approximately 2:00 PM, the surveyor asked Testing Personnel #1 for an estimate of what percentage of patient CBC's were performed in the MC mode; Testing Personnel estimated 50-60%. The surveyor then asked for a sampling and requested the charts of patients with CBC's on 7/14/2022 when three levels of QC were outside acceptable ranges. The interview continued at 2:30 PM when the surveyor and Testing Personnel reviewed patient charts. On 7/14/2022 eight patient CBC's were performed; five were run in the MC mode, and three were performed in the CP mode. The surveyor explained the laboratory must implement a mechanism to ensure no patient CBC's are run in the OT/CP or MC modes when the QC performed in that sampling mode is unacceptable. .
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of Quality Assurance (QA) and Medonic M Series Hematology records, and an interview with Testing Personnel #1, the laboratory failed to follow the QA procedure to ensure quality control (QC) results were within acceptable limits each day of patient testing. The laboratory further failed to implement QA reviews to ensure daily maintenance was performed and documented, and monthly cumulative QC included data for the entire month. This was noted from the date of the previous survey (4/28/2021) to August 2022. The findings include: 1. A review of the monthly QA checklist revealed, "All Quality Control / Calibrations were performed and were within acceptable limits before patient test results were reported". The laboratory had answered "Y" [Yes] to this QA indicator every month from April 2021 through August 2022. However, the surveyor noted nine days in June and July 2021 when QC was unacceptable, and 51 patient CBC's (Complete Blood Counts) were performed. (Refer to D5481.) The surveyor further noted the laboratory had failed to investigate the cause of QC failures and implement corrective actions to prevent recurrence. 2. A review of the Medonic M Series records revealed the laboratory had failed to review maintenance requirements, and implement QA reviews to ensure all required maintenance was performed and documented. (Refer to D5429.) 3. A review of the

	Medonic M Series Hematology QC records revealed the laboratory failed to implement QA reviews to ensure data from each day of QC was included on Levy Jennings (L-J) charts or the Interlaboratory Quality Assurance Program (IQAP) reports to track for shifts and trends over time. (Refer to D5441.) 4. During an interview with on 9/29/2022 at 3:20 PM, the surveyor reviewed and confirmed the above noted findings with Testing Personnel #1. .
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 a review of a patient test report and an interview with Testing Personnel #1, the laboratory failed to ensure patient reports included correct information for all required parameters. This was noted from the previous survey (4/28/2021) through the date of the current survey (9/29/2022). The findings include: 1. On 9/29/2022 at 3:50 PM, the surveyor reviewed the post-analytical process in the facility. The clinic used paper charts for patient records (no Electronic Medical Record system), and utilized the instrument CBC (Complete Blood Count) print out from the Medonic M Series analyzer as the patient report. The surveyor requested a patient CBC for review. 2. A review of the CBC report for patient "X" revealed the following: A) Wrong laboratory name: "Morrow Clinics" B) Wrong street address number: "34885"; the correct number was actually 34867 C) The patient's first name and the initial of the last name were utilized as one of the patient identifiers. 3. During an interview on 9/29/2022 at 4:00 PM, the surveyor reviewed the CBC report with Testing Personnel #1 who confirmed the above noted findings, and stated no one had noticed the incorrect address. The US Post office had changed the street numbers "years ago after a tornado". SURVEYOR ID #32558 Licensure and Certification Surveyor