Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0688168	04/16/2025
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) Proficiency Testing (PT) records, and an interview with the Practice Manager (PM) and Testing Personnel 1 (TP1), the laboratory failed to ensure attestation statements were signed by the LD (or designee) and the TP (analysts). This was noted for seven of the seven 2023-2025 PT events. The findings include: 1. A review of the AAB-MLE records revealed no evidence of the LD and TP signatures on attestation statements for the following events: A) 2023 Hematology M1-M3 Testing Events B) 2024 Hematology M1-M3 Testing Events C) 2025 Hematology M1 Testing Event 2. During the exit interview on 04-16-2025 at 2:30 PM, the PM and TP1 confirmed the above findings.
D2123	HEMATOLOGY CFR(s): 493.851(c) (c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two

	proficiency testing events. This STANDARD is not met as evidenced by: Based on review of the American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) Proficiency Testing (PT) records, and an interview with the Practice Manager (PM) and Testing Personnel 1 (TP1), the laboratory failed to provide documentation of participation in one of the seven 2023-2025 Hematology PT events. The findings include: 1. A review of the AAB-MLE PT records revealed no documentation of the laboratory participating in the 2024 Hematology M-1 Testing Event. 2. During the exit conference interview on 04-16-2025 at 2:30 PM, the PM stated this event occurred when the TP in charge of the laboratory retired. The PM and TP1 could not remember what happened to this PT event. 3. On 4-17-2025 the CLIA State Agency contacted AAB-MLE "Tech Support". In an email dated 4-17-2025, the MLE representative confirmed the 2024 M-1 PT samples were shipped, however the laboratory did not report any scores for the event. The laboratory should have received scores of 0% due to "failure to participate".
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of the American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) Proficiency Testing (PT), and an interview with the Practice Manager (PM) and Testing Personnel 1 (TP1), the laboratory failed to ensure review and evaluation of PT results was performed and documented. This was noted for seven out of the seven 2023-2025 PT events. The findings include: 1. A review of the AAB-MLE PT records revealed no documentation of Hematology PT performance reviews from the Laboratory Director, or designee, for the following surveys: A) 2023 Hematology M1-M3 Testing Events B) 2024 Hematology M1-M3 Testing Events C) 2025 Hematology M1 Testing Event 2. The PM and TP1 confirmed the above findings during the exit conference on 04-16-2025 at 2:30 PM.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on an observation during the laboratory tour, a review of the Complete Blood Count (CBC) Quality Control (QC) package insert, and an interview with the Practice Manager (PM) and Testing Personnel 1 (TP1), the laboratory failed to write the new expiration dates on QC vials after opening. The surveyor noted three of the three levels of QC currently in use had only the open dates recorded. The findings include:

	1. During the laboratory tour on 04-16-2025 at approximately 8:48 AM the surveyor observed the three levels of CBC QC in use were labeled with the open date, "4-14-25", however the testing personnel had not recorded the new expiration date on the vials after opening. 2. A review of the Boule QC package insert revealed the QC materials should not be utilized more than 14 days after opening. 3. During an interview with TP1 on 04-16-2025 at 8:49 AM, TP1 stated TP opens a new set of QC materials every 14 days.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) (a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of the Hematology records, the analyzer operator's manual, and an interview with the Practice Manager (PM) and Testing Personnel 1 (TP1), the laboratory failed to perform calibrations on the Medonic M-Series Hematology analyzer every six months as per manufacturer's instructions. The surveyor noted no documentation for one of two calibrations due in 2024. The findings include: 1. A review of the Hematology calibration records revealed the Medonic M-Series Hematology analyzer was calibrated on on 09-14-2023 and 8-18-2024. There was no documention of the calibration performed on March 2024. 2. A review of the Medonic operator's manual indicated calibration is required at least every six months. 3. PM and TP1 confirmed the above findings during the exit conference on 04-16-2025 at 2:30 PM.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) (e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program; This STANDARD is not met as evidenced by: Based on a review of the American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) Proficiency Testing (PT) records, a lack of documentation, and an interview with the Practice Manager (PM) and Testing Personnel 1 (TP1), the surveyor determined the Laboratory Director failed to ensure the staff returned the proficiency testing results to AAB-MLE by the submission deadline, to ensure grading by the provider for the 2024 Hematology M1 testing event. This affected one of seven testing events, reviewed by the surveyor in 2023-2025. The findings include: 1. A review of the AAB-MLE PT records revealed a lack of documentation for the

	2024 Hematology M1 testing event. 2. During the exit conference interview on 04-16-2025 at 2:30 PM, the PM stated this event occurred when the TP in charge of the laboratory retired. The PM and TP1 could not remember what happened to this PT event. 3. CLIA State Agency contacted AAB-MLE tech support on 04-17-2025. The AAB-MLE representative sent an email confirming 2024 Hematology M1 testing event samples were sent to the laboratory, but no results were submitted. The laboratory should have received scores of 0% due to "failure to participate".
D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on reviews of Proficiency Testing (PT) records, Medonic M-Series Hematology analyzer records, personnel records, and interviews with the Practice Manager (PM) and Testing Personnel 1 (TP1), the surveyor determined the Technical Consultant (also the Laboratory Director) failed to provide technical and scientific oversight and direction from the date of the previous survey, 09-29-2022 to the date of the current survey, 04-16-2025. The findings include: 1. Refer to D6036.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section. This STANDARD is not met as evidenced by: Based on reviews of Proficiency Testing (PT) records, Medonic M-Series Hematology analyzer calibration records, personnel records, and interviews with the Practice Manager (PM) and Testing Personnel 1(TP1), the surveyor determined the Technical Consultant (also the Laboratory Director) failed to provide technical and scientific oversight and direction from the date of the previous survey, 09-29-2022 to the date of the current survey, 04-16-2025. The findings include: 1. A review of laboratory records revealed a lack of technical and scientific oversight and direction contributed to the following deficiencies: A) Failure to ensure PT attestation statements were signed; PT events were performed and submitted for the provider to grade; and all PT performance evaluations obtained were reviewed and documented. (Refer to D2009, D2123, D5211) B) Failure to ensure manufacturer's calibration requirement was performed and documented semi-annually on the Medonic M-Series Hematology analyzer. (Refer to D5437) C) Failure to ensure annual competencies were performed and documented for all TP performing moderate complexity testing. (Refer to D6054) 2. During the exit summation on 04-16-2025 at 2:30 PM, the lack of technical and scientific oversight and direction was discussed and confirmed by the PM and TP1.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on a review of the Testing Personnel (TP) records and an interview with the Practice Manager (PM) and Testing Personnel 1 (TP1), the Technical Consultant (TC) (also the Laboratory Director) failed to ensure competency assessments for TP performing moderate complexity testing included all six CLIA minimal regulatory requirements. The surveyor noted six of the six requirements were missing from the annual competencies. The findings include: 1. A review of the 2023-2024 TP records revealed TP competency assessments for Hematology specialty had no documentation for the six CLIA minimal regulatory requirements. The surveyor noted the missing six requirements were as follows: (1) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing. (2) Monitoring the recording and reporting of test results. (3) Review of intermediate test results of worksheets, quality control records, proficiency testing results, and preventive maintenance results. (4) Direct observation of performance of instrument maintenance and function checks. (5) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. (6) Assessment of problem-solving skills. 2. The PM and TP1 confirmed the above findings during the exit conference on 04-16-2025 at 2:30 PM.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually This STANDARD is not met as evidenced by: Based on a review of personnel evaluation records and an interview with the Practice Manager (PM) and Testing Personnel 1 (TP1), Technical Consultant (TC) (also the Laboratory Director) failed to assess and document the annual competency of individuals responsible for moderate complexity testing. This was noted for two out of two Testing Personnel's annual competencies from 2023-2024. The findings include: 1. A review of personnel records revealed the TC failed to perform and document the 2023 and 2024 annual competency assessments for two Testing Personnel listed on the CMS 209 (Laboratory Personnel Report-CLIA). 2. A further review of the personnel records revealed TP annual performance evaluations were performed by personnel not listed on the CMS 209 (Laboratory Personnel Report-CLIA). 3. During the exit conference on 04-16-2025 at 2:30 PM, the PM and TP1 confirmed the above findings.