Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0671555	03/26/2025
Name of Provider or Supplier	**Street Address, City, State**	
Monroe County Hospital	2016 South Alabama Ave, Monroeville, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) records, and an interview with the Technical Consultant (TC)/Technical Supervisor (TS)/General Supervisor (GS), the laboratory failed to implement a mechanism to verify the accuracy of the Nucleated Red Blood Cell (NRBC), a non-regulated analyte. The surveyor noted the PT evaluation failures occurred in three consecutive events out of the six events from 2023-2024. The findings include: 1. A review of the API PT records from 2023-2024 revealed the NRBC performance scores of 50 percent for the following events: A) 2023 Hematology First Event B) 2023 Chemistry Second Event C) 2023 Hematology Third Event 2. The TC/TS/GS confirmed the above findings during Day 1 exit conference on 03-25-2025 at 4:35 PM.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on a review of the environmental records, analyzer operator's manuals, and an interview the Technical Consultant (TC)/Technical Supervisor (TS)/General Supervisor (GS), the laboratory failed to ensure the room humidity was recorded within manufacturer's acceptable limits. The surveyor noted the humidity logs the laboratory utilized from the date of the last survey, 12-07-2022 to the date of the current survey, 03-26-2025, had no manufacturer's specified ranges for operating conditions. The findings include: 1. A review of the 2022-2025 environmental records revealed no humidity ranges were defined on the temperature and humidity logs for the rooms the laboratory instruments were operated during patient testing. 2. A review of the operator's manuals revealed the manufacturers' operating humidity range requirements for the following instruments. A) Beckman Coulter DxH 690T and 520 B) Beckman Coulter AU 480 C) Beckman Coulter Access 2 D) Sysmex CA 600 E) bioMrieux Vitek 2 F) bioMrieux BACT/Alert 3D G) Cepheid GeneXpert 3. The TC /TS/GS confirmed the above findings during Day 2 exit conference on 03-26-2025 at 3:55 PM.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) (a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following: This STANDARD is not met as evidenced by: Based on review of the 2023-2024 maintenance records and an interview with Technical Consultant (TC)/Technical Supervisor (TS)/General Supervisor (GS), the laboratory failed to perform and document the annual microscope maintenance. The surveyor noted there were no maintenance records for three of the three microscopes in the laboratory from 2023. The findings include: 1. A review of the 2023-2024 microscope maintenance records revealed only the 2024 maintenance records were available for review. There were no maintenance records from 2023 for the three microscopes: A). Nikon E-400 with POL B). Nikon E-400 with Phase C). Accuscope 3004 2. The TC/TS)/GS confirmed the above findings during the day 2 exit conference on 03-26-2025 at 3:55 PM.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

	This STANDARD is not met as evidenced by: Based on a review of the pipette maintenance records and an interview with the Technical Consultant (TC)/Technical Supervisor (TS)/General Supervisor (GS), the laboratory failed to perform and document the annual pipette calibration for 11 out of the 11 pipettes from 2023-2024. The findings include: 1. A review of the 2023-2024 pipette maintenance records revealed the laboratory did not perform the calibration for the following pipettes: A) Seven MLA D-TIPPER B) One MLA MACRO C) One FINNPIPETTE Gram Negative D) One FINNPIPETTE Gram Positive E) One NICHIRYO NICHIPET Tip Master 2. A further review of the pipette maintenance records revealed all pipettes were calibrated on February 26, 2025. 3. The TC/TS/GS confirmed the above findings on 03-26-2025 at 3:55 PM.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers 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 reviews of the 2023-2024 Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT) Quality Control (QC) records, the CA-600 analyzer Operator's Manual, the Policies and Procedure (P&P) Manual, and an interview with the Technical Consultant (TC)/Technical Supervisor (TS)/General Supervisor (GS), the laboratory failed to ensure two levels of quality control were performed and accepted every eight hours, prior to analyzing patient specimens and reporting the results. The surveyor noted no QC documentations for 20 out of 31 days in August 2023 and 4 out of 30 days in November 2024. The findings include: 1. A review of the QC records from the CA-600 Coagulation analyzer revealed no QC records were available to review for the following dates. A) August 4-23, 2023 CITROL 1 LOT 564855 EXP 01/23/2025 CITROL 3 LOT 556556 EXP 10/03/2024 B) November 11-14, 2024 CITROL 1 LOT 564877 EXP 02/05/2026 CITROL 3 LOT 556580 EXP 03 /21/2026 2. A review of the analyzer printouts on patient testing revealed these patient specimens were performed during the dates when no QC records were available for review. A) 82 PT and 62 APTT patients for August 2023 B) 13 PT and 7 APTT patients for November 2024 3. A review of the P&P manual revealed the laboratory's policy to run two levels of controls every eight hours for the PT and APTT testing. 4. During an interview on 03-26-2025 at 0947 AM, the TC/TS/GS stated QC were performed for those days but may have been deleted accidentally.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of Personnel records and an interview the Technical Consultant (TC)/Technical Supervisor (TS)/General Supervisor (GS), the Laboratory Director (LD) failed to assess competency at least semi-annually in the first year of patient

	testing. This was noted for 1 out of the 17 Testing Personnel (TP) listed on the CMS 209 (Laboratory Personnel Report) from 2023-2024. The findings include: 1. A review of Personnel records revealed TP14 had no documentation of the semi-annual competency assessment available for review during the survey. Only annual competencies were performed and documented for 2023 and 2024. 2. The TC/TS/GS confirmed the above findings on 03-26-2025 at 3:55 PM during the day 2 exit conference.