Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0864770	03/19/2024
Name of Provider or Supplier	**Street Address, City, State**	
Harnett County Health Department	307 W Cornelius Harnett Boulevard, Lillington, NC	

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 review of manufacturer's instructions and review of 2022, 2023, and 2024 Medonic hematology records 3/19/24, the laboratory failed to perform and document the monthly maintenance for the Medonic M-Series hematology analyzer as specified by the manufacturer for 26 of 26 months from January 2022 through February 2024. Findings: Review of the Medonic M-Series User's Manual revealed in "Section 8: Cleaning, Maintenance & Transport Section Overview Introduction This section contains information that is crucial for maintaining, transporting and storing the Medonic M-Series. ... 8.2 Monthly Cleaning Description This section describes the cleaning procedure to be used to secure the correct function of the instrument on a monthly basis. ..." The section described steps for performing the required monthly cleaning and clot prevention. Review of 2022, 2023, and 2024 Medonic hematology analyzer maintenance records revealed the laboratory failed to perform and document the manufacturer's specified monthly cleaning and clot prevention for the Medonic M-Series hematology analyzer for 12 of 12 months in 2022 and 2023, and for 2 months (January and February) in 2024.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently

	and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of 2022 and 2023 AAB (American Association of Bioanalysts) and MLE (Medical Laboratory Evaluation) proficiency testing records and interview with TP (testing personnel) #1 on 3/19/24, the laboratory director failed to review proficiency testing results for 12 of 12 events to evaluate the laboratory's performance and identify any problems requiring corrective action. Review of 2022 AAB and 2023 AAB/MLE proficiency testing records revealed: 1. No director review of the 2022 Chemistry Q1, Q2, and Q3 and the Nonchemistry Q1, Q2, and Q3 events. 2. No director review of the 2023 Chemistry M1, M2, and M3 and the Nonchemistry M1, M2, and M3 events. During interview at approximately 11:45 a.m., TP #1 confirmed the proficiency testing records were not reviewed by the laboratory director.