Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0977694	03/11/2025
Name of Provider or Supplier	**Street Address, City, State**	
Chilton Medical Associates	108 Medical Center Drive, Clanton, 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
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, policy and procedure records, and an interview with Testing Personnel #1 and #2, the Laboratory failed to ensure humidity in the room in which the Sysmex XP 300 Hematology analyzer was operated was within the manufacturer's acceptable limits. Humidity was noted below acceptable ranges for 15 days from 2023 to 2024. The findings include: 1. A review of the Sysmex XP 300 Hematology temperature records revealed Humidity was below the manufacturer's acceptable parameters (30-85%) for a total of 15 days as follows: a) 2023: 1/16, 3/20, 12/11, 12/20, 12/21 b) 2024: 1/2-1/5, 1/17, 1/18, 1/20, 12/2-12/4 2. A review of the Policies and Procedure manual and specifications of the CBC analyzer, Sysmex XP-300, revealed a proper relative Humidity during operation to be 30-85%. 3. During the exit conference on March 11, 2025, at 1:30 PM, Testing Personnel #1 and #2 confirmed the above findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) 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 Hematology Sysmex XP-300 maintenance records, a review of the Sysmex XP-300 Instructions for Use, and an interview with the Testing Personnel (TP) 1 and 2, the laboratory failed to perform the analyzer's quarterly maintenance. The surveyor noted three out of six quarterly maintenances had no documentation from 2023-2024. The findings include: 1. A review of the Hematology maintenance records revealed a place to document quarterly (every 3 months) maintenance on the Sysmex XP-300 Maintenance Log, but the only documentation of performance was from the Sysmex Service Engineer when the preventive maintenance was performed. 2. A review of the Sysmex XP-300 Instructions for Use revealed in section 12 page 12-12 under Clean SRV "... if either the counter value exceeds 4,500, or if 3 months have passed since the last maintenance, a message will appear prompting the operator to perform periodic maintenance (SRV cleaning) ..." 3. During the exit conference on 03-11-2025 at 1:30 PM, the TP #1 and #2 confirmed the above findings. They both agreed quarterly maintenance was not performed by the TP because they did not know where the procedure can be found and was never trained on how to do it.