Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2076179	06/26/2024
Name of Provider or Supplier	**Street Address, City, State**	
Dyersburg Family Walk-In Clinic, Llc	1954 St John Avenue, Dyersburg, TN	

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) 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: (1) Water quality. (2) Temperature. (3) Humidity. (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 observation of the laboratory, review of the Sysmex XP 300 operator's manual, the laboratory's environmental records, patient test reports, staff interview, and follow-up electronic communication, the laboratory failed to monitor room temperature in the area where the Sysmex XP300 Complete Blood Count with automated White Blood Cell Differential (CBC w/Diff) instrument was used from 03 /01/24 to the date of the survey on 06/26/24. The findings include: 1. Observation of the laboratory on 06/26/24 at 8:15 a.m. revealed the Sysmex XP300 (serial number B6600) used for performing patient testing for CBC w/Diff. 2. A review of the Sysmex XP 300 operator's manual revealed that the instrument required a room temperature of 15 to 30 degrees Celsius during operation. 3. A review of environmental records revealed that room temperatures were not monitored from 03 /01/24 to 06/26/24 (the survey date). 4. A review of patient test reports revealed a CBC w/Diff reported on patient number three on 04/01/24. 5. The technical consultant confirmed the survey findings during an interview on 06/26/24 at 11:30 a.m. 6. The technical consultant stated during an electronic message received on 06/27/24 at 12:47 p.m. that 860 patient CBCs were reported from 03/01/24 to 06/26/24 (date of survey) during the period when room temperatures were not monitored.

D5461	CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on laboratory observation and staff interviews, the laboratory failed to perform quality control (QC) after changing reagents on the Sysmex XP 300 CBC instrument. The findings include: 1. Observation of the laboratory on 06/26/24 at 8:15 a.m. revealed the Sysmex XP300 (serial number B6600) used for performing patient testing for CBC w/Diff. During observation, testing person three was asked to describe the protocol for performing quality control. When asked if the laboratory performed QC after reagent changes, she stated they did not. 2. The technical consultant confirmed the survey findings during an interview on 06/26/24 at 11:30 a. m.