Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0309266	08/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
Benton Family Health Care Center	6784 Hwy 411, Benton, 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
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 observation of the laboratory, review of the manufacturer's control package insert, review of laboratory policy, and staff interview, the laboratory failed to label three of three control vials used for performing quality control on the Sysmex XP-300 with an open date and a corrected expiration date. The findings include: 1. Observation of the laboratory on 08.14.2025 at 9:20 a.m. revealed the Sysmex XP-300 complete blood count (CBC) analyzer (serial number C6720) used for patient testing. Observation also revealed three levels of Sysmex Eightcheck-3WP X-TRA CBC controls (Lot 51890) that lacked an open date and a corrected expiration date. 2. A review of the manufacturer's control package insert revealed that "Opened and recapped vials and vials whose caps have been pierced will retain stability for 14 days if stored at 2-8C after being re-capped". 3. A review of the laboratory's policy titled "Quality Control/Calibration Hematology" revealed the following statement: "all control vials will be labeled with the opening date, expiration date, and initials of person preparing control samples." 4. Interview with the Chief Financial Officer on 08.14.2025 at 9:31 a.m. confirmed the above survey findings. Word key: C = degrees Celsius
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)

	(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on observation of the laboratory, a review of complete blood count quality control records, and staff interview, the laboratory failed to have a process to monitor quality control data for shifts and/or trends in May, June, and July 2025. The findings include: 1. Observation of the laboratory on 08.14.2025 at 9:20 a.m. revealed the Sysmex XP-300 analyzer (serial number C6720) used for Complete Blood Count (CBC) patient testing. 2. A review of quality control records for the Sysmex XP-300 revealed that the laboratory did not have a process for monitoring shifts or trends in May, June, and July 2025. 3. Interview with the Chief Financial Officer on 08.14.2025 at 9:31 a.m. confirmed the above survey findings.