Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2104181	06/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
Benton Medical	188 Burt Boulevard, Benton, LA	

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
D0000	A Recertification survey was performed at Benton Medical, CLIA ID 19D2104181, on June 24, 2024. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 observation by surveyor, review of maintenance logs and interview with personnel, the laboratory failed to perform monthly maintenance procedures per manufacturer's requirements for three (3) of eighteen (18) months reviewed in 2023 and 2024. Findings: 1. Observation by surveyor during the laboratory tour on June 24, 2024 at 2:28 pm revealed the laboratory utilizes the Beckman Coulter DxH 520 analyzer for Complete Blood Count (CBC) testing in the specialty of hematology. 2. Review of the laboratory's maintenance log for the Beckman Coulter DxH 520 hematology analyzer revealed the following monthly maintenance procedure: a) Clean the WBC Bath Filter 3. Further review of the 2023 and 2024 maintenance logs revealed the monthly maintenance was not performed for the following three (3) of eighteen (18) months reviewed: a) April 2023 b) March 2024 c) April 2024 4. In interview on June 24, 2024 at 2:21 pm, Testing Personnel confirmed the monthly maintenance was not performed as required by the manufacturer.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken

	when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory policy, temperature records and interview with personnel, the laboratory failed to document corrective actions performed when refrigerator temperature was not maintained between 2 - 8 degrees celsius per laboratory policy for four (4) of one hundred seventy six (176) days reviewed in 2024. Findings: 1. Review of the laboratory's policy under "Specific Preventative Maintenance Activities" revealed "Temperature readings of refrigerators, freezers, and on-board instrument temperature monitors are read once daily. Out of range temperature should be recognized and responded to with documented corrective action". 2. Review of the laboratory's refrigerator temperature logs from January 2024 through June 2024 revealed the following four (4) of one hundred seventy six (176) days reviewed showed documentation of refrigerator temperature readings outside the laboratory's acceptable range of 2 -8 degrees celsius: a) April 23, 2024: documented refrigerator temperature of 9.7 degrees celsius b) April 25, 2024: documented refrigerator temperature of 9.6 degrees celsius c) April 29, 2024: documented refrigerator temperature of 9.1 degrees celsius d) April 30, 2024: documented refrigerator temperature of 8.3 degrees celsius 3. In interview on June 24, 2024 at 2:21 pm, Testing Personnel stated the refrigerator was replaced in May 2024 due to temperature issues. Testing Personnel confirmed the laboratory did not document corrective actions for unacceptable refrigerator temperatures identified.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on review of laboratory policy, maintenance records, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Refer to D5429.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on review of laboratory policy, temperature records and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5781.