Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0648060	08/04/2026
Name of Provider or Supplier	**Street Address, City, State**	
Myrtue Medical Center Laboratory	1213 Garfield Avenue, Harlan, IA	

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) (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 review of the laboratory's Blood Bank Maintenance policy, Blood Bank Maintenance logs, and confirmed by interview with Technical Supervisor #1 (TS #1) at 1:15 pm on 08/04/2026, the laboratory failed to perform weekly maintenance on the MTS blood bank dispensers for 14 out of 31 weeks from 12/28/2025- 08/01/2026. The findings include: 1. The laboratory's Blood Bank Maintenance policy stated the lab will clean MTS Diluent 2 and MTS Diluent 2Plus dispensers weekly. 2. Review of the Blood Bank Maintenance logs revealed the laboratory did not perform weekly dispenser cleaning during the following weeks of: 01/04/2026, 01/11/2026, 01/25 /2026, 03/08/2026, 04/12/2026, 04/19/2026, 04/26/2026, 05/03/2026, 05/17/2026, 05 /24/2026, 05/31/2026, 06/21/2026, 07/12/2026, and 07/26/2026. 3. At the time of the survey, TS #1 confirmed the laboratory failed to perform weekly cleaning of the MTS dispensers during the weeks listed above.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's Blood Bank Maintenance policy, Blood Bank Maintenance logs, and confirmed by interview with Technical Supervisor #1 (TS #1) at 1:15 pm on 08/04/2026, the laboratory failed to document monthly blood bank dispenser volume checks for five out of seven months reviewed from January 2026-July 2026. The findings include: 1. The laboratory uses Ortho MTS Diluent 2 and MTS Diluent 2Plus dispensers to perform immunohematology testing. 2. The laboratory's Blood Bank Maintenance policy stated the lab will check the accuracy of the MTS Diluent 2 and MTS Diluent 2Plus dispensers monthly. 3. Review of the Blood Bank Maintenance logs revealed the laboratory did not perform accuracy checks in the months of January 2026 and March- June 2026. 4. At the time of the survey, TS #1 confirmed the laboratory failed to perform monthly accuracy checks on the MTS dispensers during the months listed above.