Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D2307836	03/10/2025
Name of Provider or Supplier	**Street Address, City, State**	
Uph Emergency Department-Marion	3301 Armar Dr, Marion, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the Laboratory Test List and Annual Volume report, proficiency testing records, and confirmed by interview with Technical Consultant #1 (TC #1) at 10:15 am on 03/06/2025, the laboratory failed to verify the accuracy of carbon monoxide testing performed on the Radiometer ABL90 test system twice annually for two out of two time periods from 08/01/2024 - 03/06/2025. The findings include: 1. The laboratory began using the Radiometer ABL90 test system to perform carbon monoxide testing in August 2024. 2. At the time of the survey, TC #1 confirmed the laboratory did not enroll in proficiency testing or perform twice annual accuracy testing for carbon monoxide testing performed on the Radiometer ABL90 test system by another method from 08/01/2024 - 03/06/2025.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:

	This STANDARD is not met as evidenced by: Based on lack of Individualized Quality Control Plan (IQCP) records, review of quality control (QC) records, and confirmed by interview with Technical Consultant #1 (TC #1) at 2:40 pm on 03/06/2025, the laboratory failed to perform two levels of QC at least once each day of patient testing for the following test systems: Cepheid GeneXpert, Immunocard Mycoplasma, and Medtox Profile-II urine drug screen panel. The findings include: 1. The laboratory began using the Cepheid GeneXpert, Immunocard Mycoplasma, and Medtox Profile-II urine drug screen panel test systems to perform patient testing in August 2024. 2. The laboratory performed QC with each new lot of tests for the Cepheid GeneXpert, Immunocard Mycoplasma, and Medtox Profile-II urine drug screen panel test systems. 3. TC #1 indicated the laboratory intended to follow the manufacturer's instructions for performing QC. 4. At the time of the survey, TC #1 confirmed the laboratory did not have an IQCP for the Cepheid GeneXpert, Immunocard Mycoplasma, and Medtox Profile-II urine drug screen panel test systems.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood shall be stored in a clean and orderly environment in a manner to prevent mix-ups. Expired blood must not be in the routine inventory. Unacceptable units must be segregated from routine inventory. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, lack of blood storage refrigerator alarm check records, and confirmed by interview with Technical Consultant #1 (TC #1) at 3:05 pm on 03/06/2025, the laboratory failed to inspect, perform, and document alarm system checks for the blood storage refrigerator from 08 /01/2024- 03/06/2025. In addition, the laboratory did not have a policy/procedure for performing and documenting alarm system checks that included the frequency with which they must be performed. The findings include: 1. The laboratory used refrigerator #3 to store two units of blood and one unit of plasma for emergency release usage in the laboratory. 2. At the time of the survey, TC #1 confirmed that the laboratory did not perform alarm checks on the blood storage refrigerator from 08/01 /2024- 03/06/2025. In addition, TC #1 confirmed that the laboratory did not have a policy/procedure for performing and documenting alarm system checks that included the frequency with which they must be performed.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and confirmed by

	interview with Technical Consultant #1 (TC #1) at 3:30 pm on 03/06/2025, the laboratory director failed to ensure the laboratory established and maintained a quality assessment program that included the four quality systems: general laboratory, pre analytical, analytical, and post analytical.