Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0038621	08/27/2024
Name of Provider or Supplier	**Street Address, City, State**	
Spencer Hospital	1200 First Avenue East, Spencer, 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
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (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. (g) The laboratory must document all control procedures performed. 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 laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 8:51 am on 08/27/2024, the laboratory failed to perform two levels of quality control each day of patient testing for the following test systems: Bio-Rad Tox-See urine drug screen, Remel Xpect Clostridium difficile, Adeza TLiQ fetal fibronectin, and Cardinal qualitative serum human gonadotropin chorionic (HCG). The findings include: 1. The laboratory performed QC with each new lot and shipment of tests and monthly for the Bio-Rad Tox-See urine drug screen test system. 2. The laboratory performed QC with each new lot and shipment of tests for the Remel Xpect Clostridium difficile, Adeza TLiQ fetal fibronectin, and Cardinal qualitative serum HCG test systems. 3. Laboratory personnel identifier #1 indicated that the laboratory intended to follow the manufacturer's instructions for performing QC. 4. At the time of the survey, the laboratory did not have an IQCP for the test systems listed above.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)

	(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of immunohematology records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 9:49 am on 08/27/2024, the laboratory failed to perform comparison studies between the automated Ortho Vision Swift and manual Ortho MTS gel card systems for immunohematology testing twice annually for two out of two semiannual time periods from 06/01/2023- 06/30/2024. The findings include: 1. The laboratory implemented and began using the Ortho Vision Swift automated analyzer to perform immunohematology testing in April 2023. 2. Personnel identifier #1 confirmed that the laboratory uses the manual Ortho MTS gel card system as a back-up test system. 3. At the time of the survey, personnel identifier #1 confirmed that the laboratory did not perform and document twice annual comparisons for the Ortho Vision Swift and manual Ortho MTS gel card test systems from 06/01/2023- 06/30/2024.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of chemistry quality control (QC) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 2:17 pm on 08/27/2024, the laboratory failed to take and document corrective action when chemistry QC fell outside the laboratory's established criteria for acceptability for one out of 29 days of patient testing in February 2024. The findings include: 1. The laboratory performs chemistry testing on the Roche Cobas 6000 instrument. 2. On 02/26/2024, level 3 chemistry QC records indicated a result of 0.00 mg/dL for the analyte, blood urea nitrogen (BUN). 3. The laboratory had an acceptable range of 64.2- 74.8 mg/dL for level 3 BUN QC. 4. At the time of the survey, personnel identifier #1 confirmed that the laboratory did not have documented corrective action for the unacceptable BUN QC from 02/26/2024.