Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0385122	12/09/2025
Name of Provider or Supplier	**Street Address, City, State**	
Burgess Health Center	1600 Diamond Street, Onawa, 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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of blood bank procedures, blood bank records, chemistry quality control (QC) records, laboratory policies and patient test reports and confirmed by interview with the General Supervisor, the laboratory failed to ensure they had written procedures for retyping blood donor units transfused to patients as specified in D5401, ensure the laboratory performed two levels of QC each day of patient testing as specified in D5447, and ensure the laboratory retyped donor units transfused to patients as specified in D5553.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of blood bank procedures and confirmed by general supervisor #1

	(GS #1) at 10:06 am on 12/9/2025, the laboratory failed to have a procedure for retyping blood donor units that are received in the laboratory and transfused to patients. The findings include: 1. The laboratory did not retype two donor units transfused to Patient A on 10/15/2025. Refer to D5553. 2. At the time of the survey, GS #1 confirmed the laboratory did not have a procedure for retyping blood donor units transfused to patients.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by: Based on review of chemistry quality control (QC) records and confirmed by general supervisor #1 (GS #1) at 2:06 pm on 12/9/2025, the laboratory failed to perform two levels of chemistry controls on five out of 31 days of patient testing from 7/1/2025 - 7/31/2025. The findings include: 1. On 7/2/2025, the laboratory only performed diabetes control 2 for the analyte, glycated hemoglobin. 2. On 7/6/2025, the laboratory only performed immunology control 3 for the analyte, c-reactive protein. 3. On 7/14/2025, the laboratory only performed multiqual control 1 for the analyte, phosphorus. 4. On 7/18/2025, the laboratory only performed IP control 3 for the analyte, thyroid stimulating hormone. 5. On 7/26/2025, the laboratory only performed IP control 3 for the analyte, salicylate. 6. At the time of the survey, GS #1 confirmed the laboratory did not perform two levels of QC on the above dates. GS #1 also confirmed the laboratory reported out patient test results on the above dates for the analytes listed.
D5553	IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f) (b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). This STANDARD is not met as evidenced by: Based on review of blood bank records and confirmed by general supervisor #1 (GS #1) at 10:06 am on 12/9/2025 the laboratory failed to document the donor unit retype for two out of two units of blood transfused on 10/15/2025. The findings include: 1. On 10/15/2025 the laboratory crossmatched and distributed two units of blood (W037925203244 and W037925181039) to Patient A. 2. The laboratory failed to document the retype of donor unit numbers W037925203244 and W037925181039. 3. At the time of the survey, GS #1 confirmed the laboratory did not have documentation of the retype for donor unit numbers W037925203244 and W037925181039. This is a repeat deficiency, previously cited on 10/26/2023.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (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 the Epoc Individualized Quality Control Plan (IQCP) and blood gas quality control (QC) records and confirmed by general supervisor #1 (GS #1) at 12:12 pm on 12/9/2025, the laboratory failed to take and document corrective action when the partial pressure oxygen (pO2) fell outside of the acceptable range for one out of three months of QC reviewed from 6/12/2025 - 12/2/2025. The findings include: 1. The laboratory's Epoc IQCP stated the laboratory would perform two levels of external QC monthly and with each new lot number or shipment of Epoc cartridges. 2. On 9/2/2025 the laboratory ran two levels of external QC on lot number 02-25147-50 of Epoc cartridges. 3. For QC lot number, 266-3-B430, Siemens established the acceptable range for pO2 as 163.1 - 220.7 mmHg. 4. For QC lot number, 266-3-B430, the laboratory accepted an out of range result of 222.2 mmHg. 5. GS #1 confirmed the laboratory did not take and document corrective action when QC fell outside of the acceptable range for lot number 02-25147-50 of Epoc cartridges.