Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
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Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 16D0385122	**(X3) Date Survey Completed** 10/26/2023
Name of Provider or Supplier Burgess Health Center	**Street Address, City, State** 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of proficiency testing (PT) records and the laboratory test list and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at 8:40 am on 10/26/2023, the laboratory failed to enroll in an approved proficiency testing program for the analytes: alkaline phophatase, albumin, total protein, amylase, iron, magnesium, thiiodothyronine (free T3), thyroxine (free T4), and thyroid-stimulating hormone (TSH). The laboratory switched proficiency testing programs in 2023, and failed to enroll in PT for the listed analytes.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by:

	Based on review of coagulation reagent lot studies and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 11:41 am on 10/26/23, the laboratory failed to retain the specific data used to calculate the normal patient mean for lot number 564602, expiration date 7/9/2024 of Innovin (prothromin time reagent). The findings include: 1. The laboratory establishes a new normal patient mean for each specific lot number of Innovin. 2. The coagulation reagent lot studies for lot number 564602, expiration date 7/9/2024 of Innovin revealed a normal patient mean of 10.7 seconds. 3. At the time of the survey, the laboratory did not have the specific data including the number of patients or the individual patient results that the laboratory used to calculate the normal patient mean.
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 proficiency testing records and the laboratory test list and confirmed by laboratory personnel #1 (refer to the Laboratory Personnel Report) at 8:40 am on 10/26/2023, the laboratory failed to verify the accuracy twice annually for two out of two time periods for the following analytes: total iron binding capacity, lactic acid, lipase, phosphorus, and beta hydroxybutyrate from 1/1/2023 - 10/26/2023. The findings include: 1. The laboratory switched proficiency testing companies in 2023. 2. At the time of the survey, the laboratory did not enroll in PT for the above analytes. Additionally, the laboratory had not verified the accuracy of the analytes by a different method.
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 review of blood bank maintenance logs and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 9:36 am on 10/26/2023, the laboratory failed to perform and document the blood bank dispenser maintenance and volume checks for four out of four weeks in June 2023. The findings include: 1. The blood bank maintenance log states that the laboratory would clean and perform volume checks of the blood bank dispenser weekly. 2. At the time of the survey, the laboratory did not perform and document the weekly maintenance in June 2023.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions;

	(b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of calibration and calibration verification records and the Dimension Hemoglobin A1C assay instructions for use, and confirmed by laboratory personnel identifiers #1 (refer to the Laboratory Personnel Report) at 10:57 am on 10/26/2023, the laboratory failed to perform calibration verification procedures every six months for three out of three time periods for the analyte, hemoglobin A1C from 1/1/2022 - 10/26/2023. The findings include: 1. The laboratory performed calibrations on the hemoglobin A1C reagent every 30 days as per the Dimension Hemoglobin A1C assay instructions for use. 2. The hemoglobin portion of the calibration used 2 calibrators and the hemoglobin A1C portion of the calibration used 5 calibrators. 3. At the time of the survey, the laboratory did not perform calibration verification procedures which included a minimal (zero) value, a mid-point value and maximum value for the analyte, hemoglobin A1C.
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). (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the Unit Type and Crossmatch Procedure, blood bank records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 9:36 am on 10/26/2023 the laboratory failed to document the donor unit retype for two out of two units of blood transfused on 6/20/2023. The findings include: 1. On 6/20/2023 the laboratory crossmatched and distributed two units of blood (W037923140577 and W037923143740) to patient A. 2. The Unit Type and Crossmatch Procedure states that each unit of blood will be retyped prior to distribution. 3. Laboratory procedure included documenting the retype of the donor units, including the forward type reactions, on the blood unit inventory log. 4. Laboratory procedure also included documenting the donor unit type on the

	crossmatch worksheet. However, the crossmatch worksheet did not include the donor unit forward type reactions. 5. The laboratory failed to document the retype of donor unit numbers W037923140577 and W037923143740 on the blood unit inventory log. 6. The laboratory did document the donor unit type on the crossmatch worksheet for both units. However, since the donor unit retype reactions are not documented on the crossmatch worksheet, it could not be verified that the laboratory had actually performed the unit retype.
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 the laboratory test list, lack of comparison records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 10: 34 am on 10/26/2023, the laboratory failed to perform twice annual comparison studies for three out of three time periods for the analytes: influenza A, influenza B, respiratory syncytial virus (RSV), SARS-CoV-2, and Clostridioides difficile (C. diff) toxin from 1/1/2022 - 10/23/2023. The findings include: 1. The laboratory performs influenza A, influenza B, RSV and SARS-CoV-2 testing on both the Biofire and Cepheid test systems. 2. The laboratory performs C. diff toxin testing using both the Biofire and TechLab C. Diff Complete test kit. 3. At the time of the survey, the laboratory did not perform comparison testing for the above analytes.