Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0385122	(X3) Date Survey Completed 06/05/2024
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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) 155 report and graded results from the American Proficiency Institute (API), the laboratory failed to successfully participate in two consecutive testing events in the subspecialty of ABO group and D (Rho) typing. The laboratory had unsatisfactory scores for 2023 events 3 and 2024 event 1. Refer to D2163.
D2163	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(g)

	Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) 155 report and graded results from the American Proficiency Institute (API), the laboratory failed to achieve satisfactory performance (100% or greater) for two consecutive testing events in the subspecialty, ABO group and D (Rho) typing. The findings include: 1. For 2023 event 3, the laboratory received an unsatisfactory performance score of 90% for the subspecialty, ABO group and D (Rho) typing. 2. For 2024 event 1, the laboratory received an unsatisfactory performance score of 90% for the subspecialty, ABO group and D (Rho) typing 3. The CASPER 155 report and graded results from API confirm the findings listed above.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) 155 report and graded results from API (2023 event 3 and 2024 event 1), the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6089.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) 155 report and graded results from the American Proficiency Institute (API), the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D2163.