Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0397019	(X3) Date Survey Completed 11/24/2025
Name of Provider or Supplier Burnett Medical Center	**Street Address, City, State** 257 W St George Ave, Grantsburg, WI	
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
D0000	A proficiency testing desk review survey was completed on November 24, 2025, the laboratory was found out of compliance with the CLIA regulations. The conditions not met: D2016 - 42 C.F.R. 493.803(a)(b)(c) Condition: Successful participation D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
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 surveyor review of the federal Certification and Survey Provider Enhanced Reports and American Proficiency Institute proficiency testing reports, and interview with a laboratory supervisor (Staff A), the laboratory failed to successfully obtain an

	80% satisfactory testing event score for the Hemoglobin A1c test for two out of three consecutive testing events, the first and third events in 2025. See D2097.
D2097	ROUTINE CHEMISTRY CFR(s): 493.841(g) (g) Failure to achieve an overall testing event score of satisfactory performance 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 surveyor review of the federal Certification and Survey Provider Enhanced Reports (CASPER) and American Proficiency Institute (API) proficiency testing (PT) reports, and interview with a laboratory supervisor (Staff A), the laboratory failed to obtain satisfactory PT scores of at least 80% for two out of three consecutive events for the Hemoglobin A1c test (analyte 0420) in the Chemistry speciality in 2025, resulting in unsuccessful PT performance. Findings include: 1a. Review of "CASPER Report 0153D", created November 4, 2025, showed the laboratory had unsuccessful performance for Hemoglobin A1c testing (analyte 0420). 1b. Review of "CASPER Report 0155D", created November 4, 2025, showed the laboratory had unsatisfactory performance for Hemoglobin A1c testing in events one and three in 2025. Event one, score 60% Event three, score 40% 2a. Review of API "Performance Summary" reports showed the following scores for Hemoglobin A1c testing in 2025: First Event, score 60% Third Event, score 40% 2b. The API "Performance Summary 2025 Chemistry - Core - 3rd Event" report identified the Hemoglobin A1c testing performance as unsuccessful. 3. During a phone call with Staff A on November 24, 2025, at 9:50 AM, Staff A confirmed the laboratory received unsatisfactory scores for Hemoglobin A1c testing for two out of three consecutive PT events in 2025 and confirmed the laboratory's Hemoglobin A1c PT performance was unsuccessful.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of American Proficiency Institute Proficiency Testing (PT) reports and interview with a laboratory supervisor (Staff A), the laboratory failed to obtain satisfactory PT scores for Hemoglobin A1c testing in the first and third events in 2025, two out of three consecutive events, resulting in unsuccessful PT performance. The laboratory director did not ensure personnel were reporting PT results accurately and proficiently to prevent unsuccessful PT performance. See D6004.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently

	and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) desk review of American Proficiency Institute (API) PT reports and interview with a laboratory supervisor (Staff A), the laboratory failed to obtain satisfactory PT scores for the Hemoglobin A1c test for two out of three consecutive PT events in 2025, resulting in unsuccessful PT performance. The laboratory director did not ensure personnel reported PT results accurately and proficiently to prevent unsuccessful PT performance. Findings include: 1. Review of the API "Performance Summary" and "Comparative Evaluation" reports for the first and third PT events in 2025 showed following: -"2025 Chemistry - Core - 1st Event" report revealed the laboratory received unacceptable Hemoglobin A1c scores for samples GLY-02 and GLY-04 resulting in a score of 60% for Hemoglobin A1c. -"2025 Chemistry - Core - 3rd Event" report revealed the laboratory received unacceptable Hemoglobin A1c scores for samples GLY-11, GLY-14, and GLY-15 resulting in a score of 40% for Hemoglobin A1c. 2. During a phone call with Staff A on November 24, 2025, at 9:50 AM, Staff A confirmed testing personnel did not report PT results for Hemoglobin A1c accurately and proficiently in first and third PT events for Chemistry in 2025.