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| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>43D0041634   | <b>(X3) Date Survey Completed</b><br><br>11/03/2025 |
| <b>Name of Provider or Supplier</b><br><br>Community Memorial Hospital                                                     | <b>Street Address, City, State</b><br><br>111 West 10th Avenue, Redfield, SD |                                                     |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |                                                                              |                                                     |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
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| <b>D2016</b>              | <p><b>SUCCESSFUL PARTICIPATION</b><br/>CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by:<br/>Based on proficiency testing (PT) record review and interview with laboratory supervisor A, the laboratory failed to achieve successful participation for the urea nitrogen (BUN) test method. Unsatisfactory results had been received in two of three PT testing events (American Proficiency Institute [API] 2025 Chemistry-Core first and third events) resulting in unsuccessful PT participation. Refer to D2096.</p> |
| <b>D2096</b>              | <p><b>ROUTINE CHEMISTRY</b><br/>CFR(s): 493.841(f)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |

(f) Failure to achieve satisfactory performance for the same analyte or test in 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 Federal proficiency testing (PT) reports 153D and 155D, the laboratory's American Proficiency Institute's (API) PT reports and interview with laboratory supervisor A, the laboratory failed to achieve a satisfactory score of 80% or above for the urea nitrogen (BUN) test method for two of three testing events (API 2025 Chemistry-Core first and third events). Findings include: 1. Review of the 10/30/25 CASPER Unsuccessful PT report 153D revealed the laboratory had received unsatisfactory scores (less than 80%) for the BUN test method in each of the two testing events listed above. Review of the 10/30/25 CASPER Individual Laboratory Profile PT report 155D report revealed the laboratory had received unsatisfactory scores of 60% in the first and third testing events for the BUN test method. Review on 10/1/25 of the individual event BUN test method scores for the two API PT events revealed: a. 2025 Chemistry-Core first event BUN results were: (i) CH-01 result was 48. The range of acceptable results was 38-47 milligrams/deciliter (mg/dl). (ii) CH-03 result was 31. The range of acceptable results was 24-30 mg/dl. b. 2025 Chemistry-Core third event BUN results were: (i) CH-14 result was 28. The range of acceptable results was 29-35 mg/dl. (ii) CH-15 result was 14. The range of acceptable results was 18-23 mg/dl. Interview on 10/7/25 via email with laboratory supervisor A revealed the PT samples had been processed in the incorrect testing mode. a. The EPOC analyzer was used as a back up analyzer for basic metabolic panels. Patient specimens were tested and reported from the EPOC analyzer. b. A review of the PT instructions revealed PT samples were to be run in the quality assurance specimen mode. c. A review of the unsuccessful PT result printouts revealed the unsuccessful PT samples were processed in the patient specimen mode.