Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D0658927	11/03/2025
Name of Provider or Supplier	**Street Address, City, State**	
Avera Weskota Memorial Medical Center	604 1st Street Ne, Wessington Springs, SD	

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 proficiency testing (PT) record review and interview with technical consultant A, the laboratory failed to achieve successful participation for the creatine kinase (CK) 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.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f)

	(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 technical consultant A, the laboratory failed to achieve a satisfactory score of 80% or above for the creatine kinase (CK) test method for two of three testing events (API 2025 Chemistry-Core first and third testing events). Findings include: 1. Review of the 10/30/2025 CASPER Unsuccessful PT report 153D revealed the laboratory had received unsatisfactory scores (less than 80%) for the CK 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 event and 0 % in the third event for the CK test method. Review on 10/1/25 of the individual event CK test method scores for the two API PT events revealed: a. 2025 Chemistry-Core first event CK results were: (i) CH-01 result was 112. The range of acceptable results was 121-182 units/liter (U/L). (ii) CH-03 result was 267. The range of acceptable results was 274-412 U/L. b. 2025 Chemistry-Core second event CK results were: (i) CH-11 result was 54. The range of acceptable results was 70-106 U/L. (ii) CH-12 result was 145. The range of acceptable results was 163-246 U/L. (iii) CH-13 result was 29. The range of acceptable results was 32-50 U/L. (iv) CH-14 result was 67. The range of acceptable results was 86-131 U/L. (v) CH-15 result was 89. The range of acceptable results was 108-162 U/L. Interview on 10/29/25 via email with technical consultant A revealed there was a potential issue with the PT samples. a. The original PT samples were thawed and repeated. The results were similar to the laboratory's reported results. b. Quality control results during the affected time period were reviewed and found to be acceptable. c. Linearity studies were performed on 9/29/25. The results were all within the acceptable ranges. d. API was notified and replacement PT samples were requested. The replacement PT samples were tested and the results were within the acceptable ranges. f. Patient specimen testing was ceased during the investigation. Previously processed and reported patient specimens from the time period were reviewed and where possible repeated.