

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0658927	(X3) Date Survey Completed 08/10/2026
Name of Provider or Supplier Avera Weskota Memorial Medical Center	Street Address, City, State 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
D0000	The following deficiencies are a result of a desk review of proficiency testing scores obtained from the national database and verified with the proficiency testing provider. The facility was found to be out of compliance with the conditions of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D2016 - 42 C.F.R 493.803 Condition: Successful participation (proficiency testing) 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 review of the CASPER proficiency testing (PT) reports 153D and 155D and

the laboratory's American Proficiency Institute (API) 2025 and 2026 PT reports, the laboratory failed to achieve successful participation in the subspecialty of routine chemistry for the total creatine kinase (CK) analyte. Unsatisfactory results for total CK had been received in three of five PT testing events (API 2025 Chemistry-Core first and third events; 2026 second event) 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 CASPER proficiency testing (PT) reports 153D and 155D, the laboratory's American Proficiency Institute's (API) 2025 and 2026 PT reports, and interview with technical consultant A, the laboratory failed to achieve a satisfactory score of 80% or above in the subspecialty of routine chemistry for the total creatine kinase (CK) analyte for three of five testing events (API 2025 Chemistry-Core first and third events; 2026 second event). Findings include: 1. Review of the 7/20/26 CASPER Unsuccessful PT report 153D revealed the laboratory had received unsatisfactory scores (less than 80%) for the total CK analyte in each of the three testing events listed above. Review of the 7/20/26 CASPER Individual Laboratory Profile PT report 155D report revealed the laboratory had received unsatisfactory scores of 60% in the 2025 first event, 0 % in the 2025 third event and 60% in the 2026 second event for the total CK analyte. Review on 7/20/26 of the individual event total CK analyte scores for the three API PT events revealed: a. 2025 Chemistry-Core first event total 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 total 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. c. 2026 Chemistry-Core second event total CK results were: (i) CH-06 result was 248. The range of acceptable results was 254-383 U/L. (ii) CH-08 results was 36. The range of acceptable results was 38-58 U/L. Interview on 8/5/26 via email with technical consultant A revealed there was a potential issue with the running of the PT samples after the stated 14 day specimen stability. a. The survey samples were received on 5/20/26 and were processed on 6/5/26, 16 days after the survey samples were received. b. The survey samples were thawed and repeated as part of the investigation. CH-06 and CH-08 repeated as 200 and 33 U/L, respectively. Both results were below the acceptable limits. c. API was notified and replacement PT samples were requested. The replacement PT samples were tested immediately upon receipt and the results were within the acceptable ranges. d. The initial PT samples were processed on total CK reagent lot # 2688 with an expiration date of 1/27. The new PT samples were run on total CK reagent lot # 2692 with an expiration date of 7/1/27. e. Quality control (QC) results during the affected time period were reviewed and found to be acceptable. Review of the peer

	QC data from May and June indicated the laboratory's means and standard deviations were within acceptable ranges. f. Patient specimen testing was ceased during the investigation.
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 a proficiency testing desk review of CASPER 153D and 155D reports and American Proficiency Institute 2025 and 2026 PT reports, the laboratory director failed to ensure corrective actions taken were sufficient to achieve successful proficiency testing participation in an HHS approved proficiency testing program. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) 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 CASPER proficiency testing (PT) reports 153D and 155D and the laboratory's American Proficiency Institute (API) 2025 and 2026 PT reports the laboratory director failed to ensure corrective actions taken were sufficient to achieve successful participation in the subspecialty of routine chemistry for the total creatine kinase (CK) analyte in three of five testing events (API Chemistry Core 2025 first and third events; 2026 second event) resulting in subsequent unsuccessful performance. Refer to D2096. Findings include: 1. The laboratory failed to achieve satisfactory scores in three of five PT testing events for the total CK analyte. 2. The laboratory director was notified of initial unsuccessful PT performance for the total CK analyte on 11/3/25 after failing to achieve satisfactory performance in 2 PT testing events (API 2025 Chemistry Core first and third testing events). 3. Corrective actions implemented as a result of initial unsuccessful PT performance were insufficient to prevent subsequent PT failure in the API 2026 Chemistry Core second testing event.