

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0407358	(X3) Date Survey Completed 11/08/2021
Name of Provider or Supplier Avera De Smet Memorial Hospital	Street Address, City, State 306 Prairie Ave Sw, De Smet, 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	<p>SUCCESSFUL PARTICIPATION 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: Based on proficiency testing (PT) record review and interview with the laboratory supervisor, the laboratory failed to achieve successful participation for the sodium test method. Unsatisfactory results had been received in two of three PT events (2021 Chemistry-Core-1st and 3rd events) resulting in unsuccessful PT participation. Refer to D2096.</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p>

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 155D and 153D, the laboratory's American Proficiency Institute (API) PT reports and interview with the laboratory supervisor, the laboratory failed to achieve a satisfactory score of 80% or above for the sodium test method for two of three events (2021 Chemistry-Core-1st Event and 2021 Chemistry-Core-3rd Event). Findings include: 1. Review of the 10/29/21 federal Unsuccessful PT Report 153D revealed the laboratory had received unsatisfactory scores (less than 80%) for the sodium test method in each of the two events identified above. Review of the 10/10/29/21 federal Individual Laboratory Profile PT report 155D and API PT 2021 Chemistry-Core-1st and 3rd event evaluation reports revealed scores of 60% and 0% respectively for the sodium test method for each event. Review of the individual API sodium test method scores for the two API PT events revealed: a. 2021 Chemistry-Core-1st event: sodium results for samples CH-02 and CH-03 were 114 and 117 millimole/liter (mmol/L) respectively. The range of acceptability was 115-124 and 118-127 mmol/L respectively. b. 2021 Chemistry-Core-3rd event were not available due to failure of the facility to participate. Interview on 10/28/21 with the laboratory supervisor revealed the laboratory had been aware of the failures. The initial failure had been investigated. The second failure was due to the laboratory failing to submit their PT results prior to the data submission date.