

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0406780	(X3) Date Survey Completed 10/25/2023
Name of Provider or Supplier Brookings Health System	Street Address, City, State 300 22nd Avenue, Brookings, 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 free triiodothyronine (T3), sodium, and chloride test methods. Unsatisfactory results had been received in two of three PT events (American Proficiency Institute 2023 Chemistry Core 1st Event, 2023 Chemistry Core 2nd Event and 2023 Chemistry Core 3rd Event) resulting in unsuccessful PT participation. Refer to D2087 and D2109.</p>
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p>

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

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 (API) PT reports and interview with the laboratory supervisor, the laboratory failed to achieve a satisfactory score of 80% or above for the sodium and chloride test methods for two of three events (API 2023 Chemistry Core 1st Event and 2023 Chemistry Core 3rd Event). Findings include: 1. Review of the 10/25/2023 CASPER Unsuccessful PT Report 153D revealed the laboratory received unsatisfactory scores (less than 80%) for the sodium and chloride test methods in each of the two events identified above. Review of the 10/25/2023 CASPER Individual Laboratory Profile PT report 155D and API PT 2023 Chemistry Core 1st and 2023 Chemistry Core 3rd event evaluation reports revealed scores of 20% and 0% for the sodium test method and scores of 0% and 0% for the chloride test method for each event. Review of the individual API sodium and chloride test method scores for the two API PT events revealed: a. 2023 Chemistry Core 1st Event sodium results: *CH-02 was 130, the acceptable range was 120-129 millimoles/liter (mmol/L). *CH-03 was 181, the acceptable range was 170-179 mmol/L. *CH-04 was 145, the acceptable range was 134-143 mmol/L. *CH-05 was 167, the acceptable range was 155-164 mmol/L. 2023 Chemistry Core 1st Event chloride results: *CH-01 was 98, the acceptable range was 87-97 mmol/L. *CH-02 was 98, the acceptable range was 86-97 mmol/L. *CH-03 was 128, the acceptable range was 11-124 mmol/L. *CH-04 was 106, the acceptable range was 93-104 mmol/L. *CH-05 was 118, the acceptable range was 103-115 mmol/L. b. 2023 Chemistry Core 3rd Event sodium results: *Results were not reported. 2023 Chemistry Core 3rd Event chloride results: *Results were not reported. Interview on 10/25/23 with the laboratory supervisor revealed the laboratory had been aware of the failures. The initial failures had been investigated. It was determined that sodium and chloride samples sat out too long before testing. The second failure was due to the laboratory supervisor being ill and unable to report the results by the deadline.

D2098

ENDOCRINOLOGY
CFR(s): 493.843(a)

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

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 (API) PT reports and interview with the laboratory supervisor, the laboratory failed to achieve a satisfactory score of 80% or above for the free triiodothyronine (T3) test method for two of three events (API 2023 Chemistry Core 2nd Event and 2023 Chemistry Core 3rd Event). Findings include: 1. Review of the 10/25/2023 CASPER Unsuccessful PT Report 153D revealed the laboratory received unsatisfactory scores (less than 80%) for the free T3 test method in each of the two events identified above. Review of the 10/25/2023 CASPER Individual Laboratory Profile PT report 155D and API PT 2023 Chemistry Core 2nd and 2023 Chemistry Core 3rd event evaluation reports revealed scores of 20% and 0% for the free T3 test method for each event. Review of the individual API free T3 test

method scores for the two API PT events revealed: a. 2023 Chemistry Core 2nd Event free T3 results: *THY-06 was 21.4, the acceptable range was 15.9-20.8 picograms /milliliter (pg/mL). *THY-07 was 7.1, the acceptable range was 4.4-6.8 pg/mL. *THY-08 was 16.0, the acceptable range was 11.6-15.3 pg/mL. *THY-10 was 11.2, the acceptable range was 7.5-10.7 pg/mL. b. 2023 Chemistry Core 3rd Event free T3 Results: *Results were not reported. Interview on 10/25/23 with the laboratory supervisor revealed the laboratory had been aware of the failures. The initial failures had been investigated. The investigation determined that particular lot number of free T3 reagent produced slightly elevated results compared to previous free T3 reagent lot numbers. The second failure was due to the laboratory supervisor being ill and unable to report the results by the deadline.