Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0407323	(X3) Date Survey Completed 05/06/2021
Name of Provider or Supplier Prairie Lakes Healthcare System	**Street Address, City, State** 401 9th Avenue Northwest, Watertown, 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 the laboratory manager, the laboratory failed to achieve successful participation for the triiodothyronine test method. Unsatisfactory results had been received in two of three PT events (College of American Pathologists [CAP] 2020 General Chemistry /Therapeutic Drugs 3rd and 2021 first events) resulting in unsuccessful PT participation. Refer to D2096.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(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 College of American Pathologists (CAP) PT reports and interview with the laboratory manager, the laboratory failed to achieve a satisfactory score of 80% or above for the triiodothyronine (T3) test method for two of three events (CAP 2020 General Chemistry/Therapeutic Drugs third and 2021 first events). Findings include: 1. Review of the 4/29/2021 CASPER Unsuccessful PT Report 153D revealed the laboratory had received unsatisfactory scores (less than 80%) for the T3 test method in each of the two events identified above. Review of the 4/29/2021 CASPER Individual Laboratory Profile PT report 155D and CAP PT 2020 General Chemistry /Therapeutic Drugs third and 2021 General Chemistry/Therapeutic Drugs first event evaluation reports revealed the laboratory had received unsatisfactory scores of 0% for the T3 test method for each event. Review of the individual event T3 test method scores for the two CAP PT events revealed: *2020 General Chemistry/Therapeutic Drugs third event T3 results were: a. CH-11 4.4 The range of acceptability was 352.9-451.2. b. CH-12 3.8 The range of acceptability was 317.5-398.2. c. CH-13 3.8 The range of acceptability was 309.6-399.1. d. CH-14 0.6 The range of acceptability was 30.7-77.0. e. CH-15 3.8 The range of acceptability was 310.3-411.7. *2021 General Chemistry/Therapeutic Drugs first event T3 results were: a. CH-01 0.6 The range of acceptability was 31.6-79.9. b. CH-02 5.3 The range of acceptability was 388.3-628.9. c. CH-03 2.9 The range of acceptability was 247.0-306.1. d. CH-04 3.1 The range of acceptability was 266.9-345.0. e. CH-05 3.0 The range of acceptability was 257.8-357.0 Interview on 4/29/21 at 1:30 p.m. with the laboratory manager revealed the laboratory had been aware of the PT failures. Her investigation determined the results had been entered with the wrong units of measurement (nanograms/milliliter versus nanograms/deciliter). The results would have been acceptable had they been reported in the correct units of measurement.