Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D0865445	01/05/2026
Name of Provider or Supplier	**Street Address, City, State**	
Family Health Center Of Eagle Butte	24337 Us Highway 212, Eagle Butte, 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)
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 Federal proficiency testing (PT) reports 153D and 155D and the laboratory's American Proficiency Institute (API) PT report, the laboratory failed

	to achieve successful participation for the hematocrit test method. Unsatisfactory results for hematocrit in two of three PT testing events (API 2025 Hematology /Coagulation first and third events) resulting in unsuccessful PT participation. Refer to D2130.
D2130	HEMATOLOGY CFR(s): 493.851(f) (f) Failure to achieve satisfactory performance for the same analyte in two consecutive 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 (API) PT reports and interview with the laboratory director, the laboratory failed to achieve a satisfactory score of 80% or above for the hematocrit test method for two of three testing events (API 2025 Hematology/Coagulation first and third events). Findings include: 1. Review on 12/29 /25 of the CASPER Individual Laboratory Profile PT report 155D report revealed the laboratory had received unsatisfactory scores of 0% in the API 2025 Hematology /Coagulation first event and 60% in the third event for the hematocrit test method. Review on 12/29/25 of the individual event hematocrit test method scores for the two API PT events revealed: a. 2025 Hematology/Coagulation first event hematocrit results were: (i) HSY-01 result was 29.0%. The range of acceptable results was 26.5-28.8%. (ii) HSY-02 result was 40.2%. The range of acceptable results was 36.3-39.4%. (iii) HSY-03 result was 16.9%. The range of acceptable results was 15.3-16.7%. (iv) HSY-04 result was 53.7%, The range of acceptable results was 48.9-53.0%. (v) HSY-05 result was 49.6%. The range of acceptable results was 44.9-48.7%. b. 2025 Hematology/Coagulation third event hematocrit results were: (i) HSY-13 result was 30.6. The range of acceptable results was 27.7-30.1%. (ii) HSY-14 result was 17.2%. The range of acceptable results was 15.6-17.0%. Interview on 1/5 /26 via email with the laboratory director revealed: a. Review of the 2025 first Hematology/Coagulation PT event results revealed a significant positive bias for the hematocrit test method. (i) Annual analyzer maintenance had been performed by the service technician. (ii) The analyzer had been recalibrated. b. Review of the 2025 third Hematology/Coagulation PT event results revealed a significant positive bias for the hematocrit test method. (i) Patient testing was ceased. Previous patient results were reviewed. No impact on patient results had been identified. (ii) The analyzer's service department had been contacted. Recommended maintenance had been performed. (iii) The analyzer was recalibrated.