Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D0865445	09/05/2018
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
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 reports, the laboratory failed to achieve successful participation for the test method white blood cell differential. Unsatisfactory results had been received in three of three PT events (Hematology /Coagulation: 2017 3rd event and 2018 1st and 2nd events) resulting in subsequent unsuccessful PT participation. Refer to D2130.
D2130	HEMATOLOGY CFR(s): 493.851(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 and the laboratory's American Proficiency Institute (API) PT reports the laboratory failed to achieve satisfactory proficiency testing (PT) performance for the white blood cell differential test method in three of three consecutive events (Hematology /Coagulation: 2017 3rd event and 2018 1st and 2nd events) resulting in subsequent unsuccessful performance. Findings include: 1. Review of the 9/10/18 federal Unsuccessful PT Report 153D revealed the laboratory had received unsatisfactory scores (less than 80%) for the automated differential test method in each of the three events identified above. 2. Review of the federal Individual Laboratory Profile PT Report 155D on 9/10/18 and the API Performance Summary report revealed scores for the white blood cell differential test method were less than the 80% required to pass an event per Clinical Laboratory Improvement Amendment (CLIA) requirements found at CFR 493.861(a): a. 2017 Hematology/Coagulation 3rd event score = 67% (HSY-11, 12 and 15 were graded as unacceptable). b. 2018 Hematology/Coagulation 1st event score = 73% (HSY-01, 02 and 04 were graded as unacceptable). c. 2018 Hematology/Coagulation 2nd event score = 53% (HSY-07, 08, and 10 were graded as unacceptable).
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: The laboratory director failed to provide overall management of the laboratory by failing to ensure an acceptable level of analytical performance was maintained for white blood cell differentials. (See D6023).
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that 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 federal proficiency testing (PT) reports 153D and 155D and the laboratory's American Proficiency Institute (API) PT reports the laboratory director failed to ensure an acceptable level of analytical performance was maintained for the white blood cell differential test method in three of three consecutive events

	(Hematology/Coagulation: 2017 3rd event and 2018 1st and 2nd events) resulting in subsequent unsuccessful performance. Findings include: 1. The laboratory failed to achieve satisfactory scores in 3 of 3 consecutive PT testing events for the white blood cell differential test method. 2. The laboratory director was notified of initial unsuccessful PT performance for white cell differential test method on 5/21/18 after failing to achieve satisfactory performance in 2 consecutive PT testing events (event 3 2017 and event 1 2018). 3. Corrective actions implemented as a result of initial unsuccessful PT performance were insufficient to prevent subsequent PT failure.