Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0403795	08/17/2021
Name of Provider or Supplier	**Street Address, City, State**	
Bois Forte Medical Clinic	5219 St John'S Drive, Nett Lake, MN	

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 a review of Center for Medicare and Medicaid Services (CMS) reports and Medical Laboratory Evaluation (MLE) proficiency testing reports, the laboratory failed to successfully participate in proficiency testing (PT) in 2020 and 2021 for Cell ID / White Blood Cell Differential, under the specialty of Hematology. Findings include: 1. The CMS CASPER Report 0155D and MLE PT Performance Summary, reviewed on August 16, 2021, indicated the the laboratory failed to successfully participate in Cell ID / White Blood Cell Differential testing in two testing events in 2020 and 2021. Unsatisfactory PT performance in White Blood Cell Differential was obtained in the following events: -2020 3rd event 60% -2021 2nd event 40% 2. The

	CMS CASPER Report 0155D and MLE PT Performance Summary indicated the laboratory failed to obtain successful Cell ID / White Blood Cell Differential scores of at least 80 percent in two out of three consecutive testing events in 2020 and 2021. See D2121 and D2130. .
D2121	HEMATOLOGY CFR(s): 493.851(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 proficiency testing (PT) reports from Center for Medicare and Medicaid Services (CMS) and Medical Laboratory Evaluation (MLE), the laboratory failed to obtain a PT score for Cell ID / White Blood Cell Differential of at least 80 percent which resulted in unsatisfactory performance for the analyte. Findings include: 1. The CMS CASPER Report 0155D and MLE PT Performance Summary, reviewed on August 16, 2021, indicated the the laboratory failed to obtain Cell ID / White Blood Cell Differential successful scores of at least 80 percent in two testing events in 2020 and 2021. 2. The MLE Performance Summary confirmed the laboratory failed to obtain a Cell ID / White Blood Cell Differential PT score of at least 80 percent in two testing events in 2020 and 2021. -2020 3rd event 60% -2021 2nd event 40% .
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 proficiency testing (PT) reports from the Center for Medicare and Medicaid Services (CMS) and the Medical Laboratory Evaluation (MLE), the laboratory failed to achieve successful PT performance for Cell ID / White Blood Cell Differential testing in two of three consecutive PT events in 2020 and 2021. Findings include: 1. The CMS CASPER Report 0153D, reviewed on August 16, 2021, indicated the laboratory failed to obtain Cell ID / White Blood Cell Differential PT successful scores of at least 80 percent in two out of three consecutive testing events in 2020 and 2021. 2. The MLE Performance Summary confirmed the laboratory failed to obtain a Cell ID / White Blood Cell Differential PT score of at least 80 percent in two testing events in 2020 and 2021. -2020 3rd event 60% -2021 2nd event 40% .