

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 24D0403795	<b>(X3) Date Survey Completed</b> 09/14/2023
<b>Name of Provider or Supplier</b> Bois Forte Medical Clinic	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The Bois Forte Medical Clinic laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey performed on September 14, 2023. The following standard-level deficiencies were cited: 493.1105 Retention requirements 493.1236 Evaluation of proficiency testing performance .
<b>D3037</b>	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to retain microscopic examination verification of accuracy records for at least two years in 2022. Findings are as follows: 1. The laboratory performed Potassium Hydroxide (KOH) microscopic examinations as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a.m. on 09/14/23. 2. The Laboratory performed proficiency testing using the Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing provider in 2022. KOH testing was evaluated using the WSLH MiscQA_POC package. 3. The attestation statement and testing records for the WSLH 2022 MiscQA_POC2 event were not found in laboratory records. The laboratory was unable to provide the missing documents upon request. 4. The laboratory performed approximately 1 KOH examination annually as indicated on Form CMS-116 Clinical Laboratory Improvement Amendments (CLIA) Application for Certification provided by the laboratory on date of survey. 5. In an interview at 12:05 p.m. on 09/14/23, TP1 confirmed the above finding. .</p>
<b>D5211</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p>

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the laboratory failed to review proficiency testing (PT) results for one of two Microbiology PT events completed in 2022. Findings are as follows: 1. The laboratory performed Potassium Hydroxide (KOH) microscopic examinations as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a.m. on 09/14/23. 2. The Laboratory performed proficiency testing using the Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing provider in 2022. KOH testing was evaluated using the WSLH MiscQA\_POC package. 3. The results from the WSLH 2022 MiscQA\_POC2 PT event were not found in laboratory records. The laboratory was unable to provide evidence of PT result review for this event upon request. 4. The laboratory performed approximately 1 KOH examination annually as indicated on Form CMS-116 Clinical Laboratory Improvement Amendments (CLIA) Application for Certification provided by the laboratory on date of survey. 5. In an interview at 12:05 p.m. on 09/14/23, TP1 confirmed the above finding. .

**D5217**

EVALUATION OF PROFICIENCY TESTING PERFORMANCE  
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the laboratory failed to perform and document activities used to verify the accuracy of one of two microscopic examinations and two of two chemistry tests performed in the laboratory at least twice annually in 2022. Findings are as follows: 1. The laboratory performed Urine Sediment microscopic examinations and Microalbumin and Creatinine chemistry testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a.m. on 09/14/23. 2. The Laboratory performed proficiency testing using the Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing provider in 2022. 3. Twice annual Urine Sediment, Microalbumin, and Creatinine accuracy verification documentation was not found for 2022 during review of WSLH documents and laboratory records. The laboratory was unable to provide the missing accuracy verification documentation upon request. 4. The laboratory performed approximately 67 Urine Sediment examinations and Microalbumin/Creatinine ratio tests annually as indicated on Form CMS-116 Clinical Laboratory Improvement Amendments (CLIA) Application for Certification provided by the laboratory on date of survey. 5. In an interview at 12:15 p.m. on 09/14/23, TP1 confirmed the above finding.