

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D1003005	(X3) Date Survey Completed 04/12/2019
Name of Provider or Supplier Native American Community Clinic	Street Address, City, State 1213 E Franklin Ave, Minneapolis, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed ensure 2 of 5 personnel who routinely performed Hematology testing on patient samples participated in Hematology proficiency testing (PT) in 2018. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed the Laboratory Manager (LM) during a tour of the laboratory on 04/12/19 at 10:10 a.m. 2. The laboratory performed PT using the American Academy of Family Physicians (AAFP) proficiency provider. 3. Testing Personnel 1 (TP1) and Testing Personnel 2 (TP2) did not participate in 3 of 3 AAFP Hematology PT events completed by the laboratory in 2018. 4. In an interview on 04/12/19 at 12:40 p.m., the LM stated TP1 and TP2 routinely performed Hematology testing on patient samples and confirmed neither participated in PT as indicated above.</p>
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to ensure hematology proficiency testing samples were tested</p>

consistent with the number of times the laboratory routinely tested patient specimens. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Laboratory manager (LM) during a tour of the laboratory on 04/12/19 at 10:10 a.m. An ABX Micros 60 hematology analyzer was observed as present and available for use during the tour. 2. The laboratory performed proficiency testing (PT) for Hematology using the American Academy of Family Physicians (AAFP) proficiency provider. 3. Hematology PT sample HD10 from the AAFP 2018-B event and sample HD15 from the AAFP 2018-C event were tested three times each as indicated on test result documents generated by the ABX Micros 60 hematology analyzer. See below for dates and time of day testing was performed. Sample Tested on 06/26/18 HD10 4:19 4:21 4:28 Sample Tested on 10/23/18 HD15 6:20 6:24 6:34 4. In an interview on 04/12/19 at 12:45 p.m., the LM confirmed the PT samples had been tested three times and patient specimens were routinely tested twice.

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 verify the accuracy of a non-regulated Hematology analyte at least twice annually in 2017 and 2018. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Laboratory manager (LM) during a tour of the laboratory on 04/12/19 at 10:10 a.m. 2. The Fern test microscopic examination was included in the test menu provided by the laboratory. 3. Verification of accuracy for Fern testing was performed once annually in 2017 and 2018 through the American Academy of Family Physicians (AAFP) proficiency provider. The laboratory was unable to provide documentation of additional verifications upon request. 4. In an interview on 04/12/19 at 1:45 p.m., the LM confirmed the accuracy of the Fern test microscopic examination had not been verified twice annually in 2017 and 2018.

D5801

TEST REPORT
CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:
. Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of manually entered test results in 2018. Findings are as follows: 1. The laboratory manually entered test results from non-interfaced test systems into the Centricity Electronic Medical Record (EMR). 2. The Laboratory Audit Procedure located in the Quality Assurance manual indicated the accuracy of

manually entered test results was verified quarterly via chart audits. 3. Documentation of the quarterly verification of manually entered test results was found through September 2017. The laboratory was unable to provide documentation of chart audits performed between 10/01/17 and 04/12/19 upon request. 4. In an interview on 04/12/19, at 1:50 p.m. the LM stated quarterly verification of manually entered test results was not performed after September 2017.