

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 43D0917681	<b>(X3) Date Survey Completed</b> 06/20/2019
<b>Name of Provider or Supplier</b> McIntosh Community Health Center	<b>Street Address, City, State</b> 208 Main Street, Mc Intosh, SD	
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>	A recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 6/20/19. The McIntosh Community Health Center laboratory was found not in compliance with the following requirements: D2010 and D2015.
<b>D2010</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> 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 review of proficiency testing (PT) records, Panic Value Log Sheet review, and interview with laboratory personnel A, the laboratory failed to test hematology proficiency testing samples the same number of times as patient samples in four of four American Proficiency Institute (API) Hematology/Coagulation testing events (2018 first, second, third, and 2019 first) reviewed. Findings include: 1. Review of the PT records revealed the attestation statement, signed by the analyst and the laboratory director, stated samples were tested in the same manner as patient samples. The following 2018 API first Hematology/Coagulation reported results revealed: -HSY-01- hemoglobin (Hgb) 16.4 and white blood count (WBC) 16.6. -HSY-02- Hgb 11.9 and WBC 6.7. -HSY-04- Hgb 9.4 and WBC 7.4. -HSY-05- Hgb 18.2 and WBC 3.3. The following 2018 API second Hematology/Coagulation reported results revealed: -HSY-07- Hgb 11.5 and WBC 6.4. -HSY-08- Hgb 16.3 and WBC 17.6. -HSY-09- Hgb 16.2 and WBC 12.0. -HSY-10- Hgb 9.5 and WBC 7.6. The following 2018 API third Hematology/Coagulation reported results revealed: -HSY-11- Hgb 15.3 and WBC 12.0. -HSY-12- Hgb 15.0 and WBC 17.1. -HSY-13- Hgb 9.4 and WBC 7.4. -HSY-15- Hgb 11.3 and WBC 6.7. The following 2019 API first Hematology/Coagulation reported results revealed: -HSY-02- Hgb 10.3 and WBC 7.8. -HSY-03- Hgb 16.0 and WBC 12.2. -HSY-04- Hgb 17.2 and WBC 17.3. -HSY-05- Hgb 12.0 and WBC 6.5.</p>

Review of the Panic Value Log Sheet posted on the cupboard door revealed the following: \*"Report the following critical values immediately to the reporting physician." - "Hgb under 8 or over 29." - "WBC under 2 or over 20 (child) under 2 or over 25 (adult)." Interview on 6/20/19 at 8:45 a.m. with laboratory personnel A revealed: \*She stated, "I'm a creature of habit. I run all my PT samples twice." -She would then review the results of both analyzer printouts and usually reported the results of the first printout. \*She did not keep the second analyzer printout. \*She did not routinely run patient specimens twice unless they had critical results. -She kept only the printout for the reported results. A copy of the PT and critical value policies /procedures were requested from the laboratory director. No policies or procedures were given to the surveyor prior to the end of the survey.

**D2015**

**TESTING OF PROFICIENCY TESTING SAMPLES**  
CFR(s): 493.801(b)(5)(6)

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:  
Based on the review of proficiency testing (PT) events and interview with laboratory personnel A, the laboratory failed to maintain all analyzer printouts of the test results for four of four American Proficiency Institute (API) PT Hematology/Coagulation testing events (2018 first, second, third, and 2019 first) submitted for grading. Findings include: 1. Review of the records for the PT events identified above revealed a single analyzer printout for each PT specimen reported. Interview on 6/20/19 at 8:45 a.m. with laboratory personnel A revealed:\*She stated, "I'm a creature of habit. I run all my PT samples twice." -She would then review the results of both analyzer printouts and usually reported the results of the first printout. \*She did not keep the second analyzer printout. -She kept only the printout for the reported results. A copy of the PT policy/procedure was requested from the laboratory director. No policy or procedure was given to the surveyor prior to the end of the survey.