

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 52D0899620	<b>(X3) Date Survey Completed</b> 02/17/2021
<b>Name of Provider or Supplier</b> Bridge Community Health Clinic	<b>Street Address, City, State</b> 1810 N 2nd St, Wausau, WI	
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>D5215</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of American Proficiency Institute (API) proficiency testing (PT) records and interview with a technical consultant, the laboratory did not evaluate the accuracy for fifty-one of fifty-nine "Educational Blood Cell Identification" proficiency testing results in 2019 and 2020. Findings include: 1. Review of API Hematology PT records showed the laboratory did not evaluate the accuracy for fifty-one of fifty-nine ungraded "Educational Blood Cell Identification" results in 2019 and 2020. 2. Interview with a technical consultant on February 17, 2021 at 9:00 AM, confirmed the laboratory did not evaluate the accuracy for fifty-one of fifty-nine "Educational Blood Cell Identification" PT results in 2019 and 2020.</p>
<b>D5421</b>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p>

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory records and interview with the technical consultant, the laboratory director did not review the performance specification verification records on the Pentra 60C+ hematology analyzer and Pentra C400 chemistry analyzer prior to reporting patient results. Findings include: 1. Review of laboratory records for the Pentra 60C+ hematology analyzer showed the laboratory started reporting patients on December 8, 2020. Further review showed the laboratory director reviewed and accepted the verification of performance expectations on February 12, 2021. 2. Review of laboratory records for the Pentra C400 chemistry analyzer showed the laboratory started reporting patients on December 10, 2020. Further review showed the laboratory director reviewed and accepted the verification of performance expectations on February 12, 2021. 3. Interview with the technical consultant on February 17, 2021 at 9:50 AM confirmed the laboratory director did not review and accept the verification of performance expectations for the Pentra 60C+ hematology analyzer and Pentra C400 chemistry analyzer prior to reporting patient results. This is a repeat deficiency from August 2, 2018.