

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0899620	(X3) Date Survey Completed 08/02/2018
Name of Provider or Supplier Bridge Community Health Clinic	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
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 surveyor review of proficiency testing (PT) records, lab procedures, and interview with the technical consultant, the samples for chemistry and hematology events in 2016, 2017, and 2018 were tested two times while patient samples are routinely tested once. Findings include: 1. Review of PT records for events two and three of 2016, all events in 2017, and events one and two in 2018 show two set of laboratory test results for each sample. The test results do not indicate a reason for the repeated analysis. 2. Review of lab procedures do not state that patient specimens are tested in duplicate. 3. Interview with the technical consultant on August 2, 2018 at 9:30 AM confirmed patient samples are routinely tested once and the PT samples were not tested the same number of times as patient samples.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and interview with the technical consultant, the laboratory did not have a procedure available for the chemistry</p>

	<p>analyzer and chemistry testing. Findings include: 1. Review of the laboratory procedure manual provided no evidence of a procedure for the chemistry analyzer and chemistry testing performed in the laboratory. 2. Interview with the technical consultant on August 2, 2018 at 12:30 PM confirmed no approved procedure was available for the chemistry analyzer and chemistry testing performed in the lab.</p>
<p>D5403</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the procedure for hematology testing and interview with the technical consultant, the laboratory procedure does not provide step by step instructions for performing hematology testing. Findings include: 1. Review of the "Micros 60 ABX Diagnostics" procedure for hematology testing reveals the procedure refers to the manufacturer's manual but does not include step-by-step instructions unique to this lab or specify the quality control (QC) type and frequency, calibration type and frequency, maintenance procedures, patient test reporting, and lab specific reference ranges. 2. Interview with the technical consultant on August 2, 2018 at 12:30 PM confirmed the procedure for hematology testing does not specify the step-by-step instructions specific to this laboratory and does not specify QC and calibration type and frequency, maintenance procedures, patient test reporting, and lab specific reference ranges. This is a repeat deficiency previously cited July 26, 2016.</p>
<p>D5421</p>	<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 procedures and records, manufacturer's manual, performance verification records for the Micros 60 ABX hematology analyzer, and interview with the Technical Consultant, the laboratory did not verify the reference intervals (normal values) before reporting patient results. Findings include: 1. Review of the "Micros 60 ABX Diagnostics" hematology procedure do not state the approved reference ranges that are currently in use for patient testing. The procedure states the the manufacturer's manual is the procedure. 2. Review of the reference interval (normal values) in the Electronic Medical Record (EMR) for patient reports do not match the reference intervals in the manufacturer's manual for the Micros 60 ABX hematology analyzer. The male and female reference intervals in the EMR versus the manufacturer's reference intervals do not match for the White Blood Cell, Red Blood Cell, Hemoglobin, Hematocrit, Mean Cell Volume, Mean Cell Hemoglobin, Mean Cell Hemoglobin Concentration, and Platelet analytes. 3. Review of laboratory performance verification records from the 2010 for the Micros 60 ABX hematology analyzer show that the laboratory did not perform reference interval (normal values) studies. 3. Interview with the technical consultant on August 2, 2018 at 12:30 PM confirms the reference intervals (normal values) for the Micros 60 ABX hematology analyzer were not verified prior to use for patient testing in May 2010.

D5429

MAINTENANCE AND FUNCTION CHECKS
 CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
 Based on surveyor review of the manufacturer's manual, patient result logs, and interview with the technical consultant, testing personnel have not adhered to the maintenance procedures defined by the Micros 60 ABX hematology manufacturer and did not perform weekly maintenance as required. Findings include: 1. Review of the manufacturer's manual states that concentrated cleaning is the required weekly maintenance on the ABX 60 Micros hematology analyzer. The lab documents weekly maintenance on the patient results logs. Review of 17 weeks of patient testing on the patient result logs for the months of August 2016, January 2017, May 2017, and January 2018 show that the required concentrated cleaning was not performed 10 out of the 17 weeks of patient testing. 2. Interview with the technical consultant on August 2, 2018 at 12:30 PM confirms testing personnel did not perform weekly maintenance as required on the ABX 60 Micros hematology analyzer.

D5807

TEST REPORT
 CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
 Based on surveyor review of patient test reports, electronic medical records (EMR)

and interview with the technical consultant, the reference intervals for the urine macroscopic and microscopic results are not available. Findings include: 1. Review of patient test reports in the EMR for urine macroscopic and microscopic results show that the laboratory does not list the reference intervals on the patient test reports. 2. Interview with the technical consultant on August 2, 2018 at 12:20 PM confirmed that the reference intervals for the urine macroscopic and microscopic results are not on patient test reports and in the EMR.