Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 52D2274905	**(X3) Date Survey Completed** 01/10/2024
Name of Provider or Supplier New Richmond Medical Center	**Street Address, City, State** 525 Knowles Ave, New Richmond, 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	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of laboratory procedures and Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) records and interview with the laboratory director, the laboratory did not test samples the same number of times that it routinely tests patient samples for three of five samples in 2023. Findings include: 1. Review of the "Sysmex XN-330 Results to be Verified" chart showed the following "Values that Need to be Reran" for White Blood Cells (WBC), Red Blood Cell (RBC) and Hemoglobin (HGB) for patients: Analyte/Less Than/Greater than WBC/3500 thousands per cubic millimeter (K/uL)/20,000 K/uL RBC/3.0 million per cubic millimeter (M/uL)/6.0 M/uL HGB/10.0 grams per deciliter (g/dL)/19 g/dL 2. Review of WSLH PT records for 2023 showed the following PT sample results that met repeat criteria: Sample/Results AF5-6/RBC 2.26 M/uL/HGB 5.9 g/dL A5-8/RBC 2.25 M/uL /HGB 5.8 g/dL AF5-11/RBC 2.40 M/uL/HGB 6.1 g/dL AF5-12/WBC 20.7 (20,700 K /uL) AF5-14/WBC 20.8 (20,800 K/uL) Further review showed no evidence of repeat analysis for samples AF5-6, AF5-8 and AF5-11 for RBC and HGB. 3. Interview with the laboratory director on January 10, 2024, at 10:15 AM confirmed the laboratory did not test samples the same number of times that it routinely tests patient samples in 2023.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) 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. This STANDARD is not met as evidenced by: Based on surveyor review of verification of performance specification records and interview with the laboratory director, the laboratory did not evaluate the precision, accuracy and reportable range of the test system for one of four new analyzers installed in the laboratory. Findings include: 1. Surveyor review of verification of performance specifications in the laboratory showed the Sysmex XN330 hematology analyzer, Ortho Diagnostics Vitros 3400 chemistry analyzer, Streck MiniCube erythrocyte sedimentation (ESR) rate analyzer and the BV Affirm microbial identification system as new analyzers in this laboratory. Further review showed no documentation that the laboratory evaluated the precision, accuracy and reportable range of the Streck MiniCube ESR analyzer. 2. Interview with the laboratory director on January 10, 2024, at 12:52 PM confirmed the laboratory did not evaluate the precision, accuracy and reportable range of the Streck MiniCube ESR analyzer.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on surveyor review of calibration verification records, patient testing reports and interview with the laboratory director, the laboratory did not perform calibration verification every six months for five of five analytes on the Ortho Diagnostic Vitros 3400 chemistry analyzer in 2023. Finding include: 1. Review of calibration verification records showed calibration verification performed on the Vitros 3400 chemistry analyzer during installation in January 2023 and June 15, 2023. Further review showed no evidence of additional calibration verification performed glucose,

	aspartate aminotransferase (AST) and unconjugated and conjugated bilirubin on the analyzer in 2023 when calibration verification was due on December 15, 2023. 2. Review of patient testing reports showed sixty-five patient tests were performed containing the glucose, AST and bilirubin analytes between December 15, 2023, and January 10, 2024. 3. Interview with the laboratory director on January 10, 2024, at 1: 30 PM confirmed the laboratory performed the laboratory did not perform calibration verification every six months on the Ortho Diagnostics Vitros 3400 chemistry analyzer in 2023.