Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0395391	(X3) Date Survey Completed 10/08/2024
Name of Provider or Supplier Stockbridge-Munsee Hlth & Wellness Center	**Street Address, City, State** W12802 County Hwy A, Bowler, 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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on survey review of chemistry records and procedures and interview the laboratory manager, staff A, the laboratory director did not sign and date twenty-four of twenty-four QuidelOrtho Vitros XT3400 chemistry procedures prior to patient use. Findings include: 1. Review of the QuidelOrtho Vitros XT3400 performance specification verification records showed the Vitros XT 3400 go-live date was May 28, 2024. 2. Review of the QuidelOrtho Vitros XT3400 chemistry procedures showed the laboratory director reviewed and signed the procedures on June 27, 2024. 3. Interview with the staff A on October 8, 2024, at 2:15 PM confirmed the laboratory director did not sign and date new chemistry procedures prior to patient use.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and procedures and interview with the laboratory manager, staff A, the laboratory did not maintain a copy of each procedure with the date the testing was discontinued for twenty-four of twenty-four retired chemistry procedures. Findings include: 1. Review of maintenance records for the QuidelOrtho Vitros 350 chemistry analyzer showed testing on the analyzer was

	discontinued on May 25, 2024. 2. Review of the QuidelOrtho Vitros 350 chemistry analyzer procedures showed no documentation of discontinuation of the procedures. 3. Interview with staff A on October 8, 2024, at 2:15 PM confirmed the laboratory did not maintain a copy of the procedures related to the retired chemistry analyzer with date of discontinuance.
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 laboratory records and interview with the laboratory manager, staff A, the laboratory director did not review and approve the performance specification verification records for one of one new chemistry analyzers prior to reporting patient results. Findings include: 1. Review of the validation forms for the QuidelOrtho Vitros XT 3400 chemistry analyzer showed the laboratory director signed the performance specification verifications on October 8, 2024. 2. Interview with the staff A on October 8, 2024, at 2:15 PM confirmed the laboratory went live with the QuidelOrtho Vitros XT3400 chemistry analyzer on May 28, 2024, and the director did not review and approve the performance specification verification records prior to reporting patient results.
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 laboratory records and interview the laboratory manager, staff A, the laboratory did not perform calibration verification every six months for three of three chemistry analytes on the QuidelOrtho Vitros XT3400 chemistry analyzer. Finding include: 1. Review of QuidelOrtho Vitros XT 3400 calibration verification records showed calibration verification was performed on all analytes as part of the implementation procedure on March 27, 2024. Further review showed no additional calibration verifications. 2. Review of quality control testing records showed testing was performed between September 27, 2024, when calibration verification was due, and October 8, 2024. 3. Interview with staff A on October 8, 2024, at 2:200 PM confirmed the laboratory did not perform calibration verification every six months for sodium, potassium and chloride on the QuidelOrtho Vitros XT3400 chemistry analyzer.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and Individualized Quality Control Plan (IQCP) records and interview with the laboratory manager, staff A, the laboratory did not perform positive and negative quality control on each day of patient testing for the Quidel Sofia 2 Lyme antibody testing for one of one month of patient testing and had not developed an IQCP. Findings include: 1. Review of Quidel Sofia 2 procedure stated a positive and negative control were run with each new lot of reagents. 2. Review of IQCP records showed no evidence of an IQCP specific for the Sofia. 3. Interview with staff A on October 8, 2024, at 12:10 PM confirmed the laboratory did not perform a positive and negative quality control on each day of patient testing and had not developed an IQCP for the Quidel Sofia 2 Lyme antibody test.