

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0395391	(X3) Date Survey Completed 09/28/2022
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
D5403	<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 laboratory procedures and interview with the laboratory supervisor, the procedures did not include reference intervals (normal values) for four of five test systems reviewed. Findings include: 1. Review of the 'Sysmex XP-300 Complete Blood Count Procedures', 'Microalbumin/Creatinine for use on the DCA Vantage Analyzer', 'Vitros 350 Procedure', and 'Reading and Grading Whole Blood Differentials' showed no reference intervals (normal ranges) provided in the procedures. 2. Interview with the laboratory supervisor (staff A) on September 28, 2022 at 10:25 AM confirmed the hematology procedures for the Sysmex analyzer and</p>

for manual differentials did not include reference ranges. Further interview confirmed the procedure manual did not include procedures for each of the analytes performed on the Vitros 350 analyzer and that the analyzer procedure did not include reference intervals for the analytes tested in the laboratory. The supervisor also confirmed the Vantage Microalbumin / Creatinine procedure did not include a reference range for the MA/CR (Microalbumin Creatinine Ratio). This is a repeat deficiency previously cited on August 30, 2018.

D5437

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:
Based on surveyor review of calibration records for four analytes tested on the Vitros 350 analyzer and manufacturer's instructions and interview with the laboratory supervisor, the laboratory did not calibrate or perform calibration verification for three of the four analytes every six months as required by the manufacturer. Findings include: 1. Review of the Vitros 'Instructions for Use' showed the following calibration requirements in the 'When to Calibrate' section for Amylase, Blood Urea Nitrogen and Cholesterol, "When government regulations require. For example, in the USA, CLIA regulations require calibration or calibration verification at least once every six months." 2. Review of calibration records for Amylase, AST (aspartate aminotransferase), Blood Urea Nitrogen, and Cholesterol showed the laboratory did not calibrate the Amylase, Blood Urea Nitrogen and Cholesterol assays every six months. Amylase: Lot 6011-4662 calibrated January 26, 2021, new calibration due July 26, 2021 Lot 6016-0394 calibrated November 2, 2021, new calibration due May 2, 2022 Lot 6019-7769 calibrated June 28, 2022 Blood Urea Nitrogen: Lot 0131-2820 calibrated December 17, 2020 new calibration due June 17, 2021 Lot 0131-7477 calibrated July 7, 2021, new calibration due January 7, 2022 Lot 0131-4328 calibrated March 30, 2022 Cholesterol: Lot 0845-4413 calibrated March 2, 2021 for Quality Control issues, new calibration due September 2, 2021 Lot 0845-4413 calibrated January 20, 2022 for six-month calibration, new calibration due July 20, 2022 No additional calibration records are available for these analytes and no records are available showing the laboratory performed calibration verification evaluations for these assays when they did not perform calibrations within six months of the last calibration. 3. Interview with the laboratory supervisor (staff A) on September 28, 2022 at 1:45 PM confirmed the laboratory did not calibrate or perform calibration verification every six months as required for testing on the Vitros 350 analyzer.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on surveyor review of laboratory records, procedures, manufacturer's documentation, and patient reports, manual calculations, and interviews with laboratory staff, the director did not provide overall management and direction in accordance with 493.1407 of this subpart. Findings include: 1. The director did not implement a quality assessment program that ensured verification of the INR (International Normalized Ratio) calculation. The laboratory reported inaccurate patient INR results in 2021 and 2022. See D6021, item 1. 2. The director did not implement a quality assessment program to ensure timely calibration of chemistry assays performed on the Vitros 350 analyzer. See D6021, item 2. 3. The director did not ensure that approved procedures were available for each of the chemistry assays performed on the Vitros 350 analyzer. See D6031.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory records, performance of manual calculations and interview with the laboratory supervisor, the laboratory director did not ensure the laboratory established an ongoing quality assessment procedure to ensure verification of the accurate calculation of the International Normalized Ratio (INR) in 2021 or 2022. Findings include: 1. Review of the coagulation 'Protime QC' worksheets in the laboratory showed the following patient INR results were reported: Patient / Date / INR result Patient 1 / June 15, 2021 / 2.68 Patient 2 / November 16, 2021 / 3.56. Patient 3 / August 4, 2022 / 3.26 2. Manual calculation of the INR value for the patients identified in finding one using the patient mean and ISI (International Sensitivity Index) values shown on the laboratory worksheets: Patient / Calculated INR / Worksheet (Reported) INR Patient 1 / 2.46 / 2.68 Patient 2 / 3.09 / 3.56 Patient 3 / 2.82 / 3.26 3. Interview with the laboratory supervisor on September 28, 2022 at 12:45 PM confirmed laboratory personnel did not verify the calculation of the INR result and the director did not ensure the laboratory had quality assurance procedures in place to verify that the laboratory accurately calculated the reported INR values. Item 2: Based on surveyor review of laboratory records and manufacturer's instructions and interview with the laboratory supervisor, the laboratory director did not develop a quality assurance program to ensure personnel performed calibrations or calibration verifications every six months for analytes on the Vitros 350 analyzer. Findings include: 1. Review of calibration records for four analytes tested using the Vitros 350 analyzer showed the laboratory did not calibrate the assays or verify the calibrations every six months for three of the four analytes. See D5437. 2. Interview with the laboratory supervisor (staff A) on September 28, 2022 at 1:45 PM revealed

the laboratory did not have a quality assurance process to ensure personnel completed Vitros 350 calibrations every six months as required.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(13)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory procedures, patient reports, and manufacturer's instructions and interview with the supervisor, the laboratory director did not ensure the laboratory had approved procedures for the twenty-three individual assays performed on the Vitros 350 analyzer. Findings include: 1. Review of laboratory procedures revealed a procedure for the Vitros 350 analyzer, 'Vitros 350 Procedure'. The procedure did not include any specific information for the individual tests performed on the Vitros 350 (Albumin, Alkaline Phosphatase, Alanine Transaminase (ALT) , Amylase, Aspartate Aminotransferase (AST), Bilirubin: Total and Direct, Calcium, Chloride, Cholesterol: High Density Lipoprotein (HDL) and Total, Carbon Dioxide (CO2), Creatinine, Glucose, Lipase, Magnesium, Phosphorus, Potassium, Sodium, Total Protein, Triglycerides, Urea Nitrogen (BUN), and Uric Acid) including specific specimen handling requirements, calibration, interfering substances, and reference or reportable ranges. 2. During an interview with the laboratory supervisor (staff A) on September 28, 2022 at 10:25 AM, the supervisor stated the laboratory uses the manufacturer's instructions for their individual procedures. The manufacturer's instructions showed no evidence of review or approval by the laboratory director. 3. Comparison between the manufacturer's instructions and patient reports showed the reference ranges identified by the manufacturer did not consistently match those used by the laboratory. 4. Interview with staff A at 11:00 AM on September 28, 2022 confirmed the laboratory director did not ensure approved procedures were available for the twenty-three individual assays performed on the Vitros 350 analyzer.

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY

CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on surveyor review of laboratory records and manufacturer's documents, manual calculations, and interview with laboratory personnel, the technical consultant did not provide needed technical oversight in accordance with 493.1413 of this subpart. Findings include: 1. The technical consultant did not identify staff training needs regarding required changes for instrument settings on the BFTII coagulation analyzer when Innovin reagent lot number changes occurred. See D6045. 2. The

technical consultant did not evaluate testing personnel competency in performing microscopic evaluations. See D6046. 3. The technical consultant did not monitor reporting of INR (International Normalized Ratio) results to ensure accurate reporting. See D6048. 4. The technical consultant did not monitor coagulation worksheets to identify errors and ensure staff competency. See D6049.

D6045

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(7)

(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

This STANDARD is not met as evidenced by:
Based on surveyor review of laboratory records, observation of the coagulation analyzer, and interview with testing personnel, the technical consultant did not identify staff training needs regarding required changes for instrument settings on the BFTII analyzer when Innovin reagent lot number changes occurred. Findings include:
1. Observation on September 28, 2022 at 12:45 PM of Innovin reagent used for prothrombin time and INR testing showed lot number 564604 was in use.
2. Observation of the coagulation analyzer on September 28, 2022 at 12:45 PM with testing personnel (staff A) revealed staff could not access the ISI (International Sensitivity Index) or the mean (average) normal patient value settings in the analyzer.
3. Interview with testing personnel on September 28, 2022 at 12:45 PM confirmed the INR (International Normalized Ratio) result was calculated by the analyzer using the ISI and mean normal patient values. Further interview confirmed the analyzer was not calculating the correct INR values for patient tests and that the ISI and mean normal patient values had not been updated in the analyzer when the current Innovin lot number was put in use on September 12, 2022.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on surveyor review of competence evaluation records and interview with the laboratory supervisor, the laboratory did not evaluate competency for four of four testing personnel in performing microscopic evaluations in 2021 or 2022. Findings include: 1. Review of competence evaluation records showed no evidence of microscopic urinalysis, manual white cell differentials, potassium hydroxide (KOH), or vaginal wet mount evaluations. The 2022 'Checklist for Competency Assessment Lab Techs' form showed evaluation of four testing personnel in using the nine analyzers in the laboratory. The form did not include microscopic evaluations. 2. Interview with the laboratory supervisor (staff A) on September 28, 2022 at 10:25 AM confirmed the technical consultant had not evaluated the competency of testing personnel in performing microscopic examinations in 2021 or 2022.

D6048

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(ii)

The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory records, manual calculations and interview with the laboratory supervisor, the technical consultant did not monitor reporting of INR (International Normalized Ratio) test results to evaluate competency and ensure accurate INR calculations for the fifty-six patients testing in 2021 or in 2022. Findings include: 1. Review of four patient records recorded on the coagulation 'Prottime QC' worksheets showed the following: Patient / Date tested / INR reported Patient 1 / June 15, 2021 / 2.68 Patient 2 / November 16, 2021 / 3.56 Patient 3 / August 4, 2022 / 3.26 Patient 4 / September 19, 2022 / 4.24 3. Manual calculation of the INR value for the patients identified in finding 1 using with the patient mean and ISI values shown on the manufacturer's documentation: Patient / calculated INR / reported INR patient 1 / 2.82 / 2.68 patient 2 / 3.09 / 3.56 patient 3 / 2.46 / 3.26 patient 4 / 3.89 / 4.24 4. Review of a report showing test volumes from January 1, 2021 through December 31, 2021 showed the laboratory reported fifty-six patient INR results during 2021. 5. Interview with the laboratory supervisor (staff A) on September 28, 2022 at 12:45 PM confirmed the technical consultant did not monitor patient INR results to ensure accurate result reporting.

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on surveyor review of manufacturer's documentation and coagulation worksheets and interview with the laboratory supervisor, when reviewing worksheets to evaluate competency, the technical consultant did not identify errors on six of six reviewed coagulation worksheets. Findings include: 1. Review of the manufacturer's documentation showed the following lot specific ISI (International Sensitivity Index) values for the BFT II analyzer: Innovin lot / ISI Value / Expiration Date 549730 / 0.89 / June 21, 2021 549759 / 0.93 / August 22, 2022 564604 / 0.92 / September 9, 2024 2. Review of coagulation 'Prottime QC' worksheets showed documentation of Prothrombin Time (Prottime) and INR testing and quality control (QC). The worksheets showed the Innovin reagent lot number, expiration date, the average (mean) prottime value for normal patients, and the ISI for the lot in use. The worksheets included the statement, "Prottime controls will be on the analyzer no longer than 6 hours a workday and are good for 4 days." Personnel also record patient test results on the worksheets. Review of the worksheets during the survey identified the following errors with no indication the technical consultant noted the errors during review: June 2021 The worksheet showed Lot 549730, ISI 0.92 was in use during June 2021. (The ISI value does not match the value of 0.89 from the manufacturer's documentation.) The worksheet showed the random platelet poor plasma count was 21 (The laboratory reports platelet counts times 1,000, resulting in a 21,000 count) and

shows the acceptable range was less than 10,000. There is no indication the unacceptable value was noted or that any corrective action was taken. Personnel performed testing on June 4, 10, 11, and 15. There is no indication of when new control bottles were used to confirm controls were not used past their open expiration date. October 2021 The worksheet showed the lot number in use was 549730 with an expiration date of June 21, 2021, four months prior. November 2021 Testing personnel recorded the patient INR value in the protime result section and the protime results in the INR section on November 30, 2021. Personnel crossed off the printed Innovin reagent information and hand-wrote the current lot information onto the worksheet without taking corrective actions for previous worksheets. Personnel performed testing on November 3, 5, 16, and 30. There is no indication of when new control bottles were used. July 2022 Personnel performed testing on July 6, 20, and 26. There is no indication when new control bottles were used. August 2022 Personnel performed testing on August 1, 4, 10, 11, and 22. There is no indication of when new control bottles were used. September 2022 The worksheet showed Lot 549759A, ISI 0.79, mean of normal range 9.8 expiration date August 22, 2022 was in use during September 2022. The ISI value does not match the value of 0.93 from the manufacturer's documentation. The INR values on the worksheet do not show the laboratory used the 0.79 ISI for calculation of patient INR results. Personnel performed testing on September 12, 15, 16, 22, 23, and 26. There is no indication of when new control bottles were used. 3. Interview with the laboratory supervisor (staff A) on September 28, 2022 at 12:45 PM confirmed the technical consultant did not identify the errors on the worksheets during their reviews.