Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0395391	08/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Stockbridge-Munsee Hlth & Wellness Center	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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records and test volumes, and interview with testing personnel the laboratory does not verify the accuracy of the potassium hydroxide (KOH) testing performed on skin scrapings twice annually. Findings include: 1. Review of PT records showed the laboratory does not participate in a program that includes testing of skin scrapings with KOH. 2. Test volume records showed 15 KOH tests were performed in the last year. 3. Interview with testing personnel, staff A, on August 30, 2018 at 9:30 AM confirms the laboratory does not verify the accuracy of KOH testing of skin scrapings twice annually.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on surveyor review of hematology procedures and survey forms, and interview with testing personnel, the procedures for manual differential do not include reporting limitations required for moderate complexity testing. Findings include: 1. Review of the "Reading and Grading Whole Blood Smear Differentials" procedure showed the procedure was updated August 7, 2017. The procedure includes instructions for reporting abnormal red cell morphology and inclusions and white cell abnormalities and immature forms. 2. Review of the Center for Medicare and Medicaid Services (CMS) Form 209, Laboratory Personnel Report (CLIA), signed by the laboratory director on August 30, 2018, showed the laboratory only performs moderate complexity testing. 3. Interview with testing personnel, staff A, on August 30, 2018 at 11:45 AM confirmed the laboratory should not perform high complexity testing. Further interview confirms the differential procedure does not include limitations to prevent this laboratory from reporting results that are limited to laboratories performing high complexity testing.
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 surveyor review of hematology procedures and interview with testing personnel, updates to the procedure for manual differentials were not approved by the laboratory director before use. Findings include: 1. Review of the "Reading and Grading Whole Blood Smear Differentials" procedure showed the procedure was updated August 7, 2017. The procedure shows no evidence of review or approval by the laboratory director. 2. Interview with testing personnel, staff A, on August 30, 2018 at 11:45 AM confirmed the revised procedure was not approved by the laboratory director before use. This is a repeat deficiency. D5407 was previously cited on July 27, 2016.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation of the coagulation analyzer, review of manufacturer's instructions, and interview with testing personnel, the laboratory has used coagulation

	reagents beyond the expiration date. Findings include: 1. Observation of the Dade BFTII coagulation analyzer in the laboratory on August 30, 2018 at 10:40 AM revealed Innovin reagent available on the analyzer. Later observation at 1:30 PM revealed Innovin was on the analyzer and was warmed to 37 degrees C (Celsius). 2. Review of the Dade Innovin manufacturer's instructions showed the reconstituted reagent has a 24 hour expiration date when stored at 37 degrees. 3. Interview with testing personnel, staff A, at 1:30 PM on August 30, 2018 confirmed the reagent is stored at 37 degrees C for approximately eight hours during the day. Further interview revealed the reagent is reconstituted on Monday morning, maintained at 37 degrees during the day, and then refrigerated overnight and the same reagent is routinely used Monday through Friday. Staff A agreed the reagent would have been at 37 degrees for 24 hours after the third day and the reagent was used after the expiration date. This is a repeat deficiency. D5417 was previously cited on August 19, 2014 and September 15, 2010.
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 testing personnel, the laboratory did not demonstrate that it could obtain performance specifications comparable to those established by the manufacturer before testing patient samples. Findings include: 1. Review of laboratory records shows the laboratory obtained a replacement DCA Vantage analyzer. Analyzer records show the new analyzer has been used since June 2017 for urine microalbumin testing. 2. Interview with testing personnel, staff A, on August 30, 2018 at 11:00 AM confirmed the laboratory did not evaluate the precision, accuracy and reportable range of the analyzer or verify the reference ranges were appropriate before testing with the new analyzer.
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 laboratory records and interview with testing personnel, the laboratory has not documented periodic maintenance as required by the manufacturer. Findings include: 1. Review of maintenance logs for the hematology analyzer show cleaning of the sample rotor valve is required quarterly. The last documented cleaning was performed on February 12, 2018. In 2017 cleaning was not documented between February 17, 2017 and October 25, 2017. 2. Interview with staff

	A on August 30, 2018 at 11:45 AM confirmed the maintenance was not documented as required.
D5547	HEMATOLOGY CFR(s): 493.1269(c)(d) (c) For manual coagulation tests-- (c)(1) Each individual performing tests must test two levels of control materials before testing patient samples and each time a reagent is changed; and (c)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on surveyor review of coagulation testing records and interview with testing personnel, each individual performing manual coagulation tests did not test two levels of control materials before testing patient samples. Findings include: 1. Review of coagulation testing records from January 2018 show controls were tested on January 2, 2018 by staff A and two patients were tested by staff B. On January 8 and 29, 2018 controls were tested by staff A, and one of two patients were tested by staff B. 2. Interview with testing personnel, staff A, on August 30, 2018 at 10:40 AM confirmed the laboratory performs manual coagulation testing and has not ensured each individual tests two levels of controls prior to testing patient samples.