Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 52D0395391	**(X3) Date Survey Completed** 09/17/2025
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**
D0000	A proficiency testing desk review survey was completed on September 17, 2025, the laboratory was found out of compliance with the CLIA regulations. The conditions not met: D2016 - 42 C.F.R. 493.803(a)(b)(c) Condition: Successful Participation D6000 - 42 C.F.R. 493.1403 Condition: Moderate Complexity Laboratory Director
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on surveyor review of the federal Certification and Survey Provider Enhanced Reports and American Proficiency Institute proficiency testing reports and interview

	with the Technical Consultant (Staff A), the laboratory failed to successfully obtain an 80% satisfactory testing event score for the prothrombin time test for two of two consecutive events, the first and second events in 2025. See D2130.
D2130	HEMATOLOGY CFR(s): 493.851(f) (f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on surveyor review of federal Certification and Survey Provider Enhanced Reports (CASPER) and American Proficiency Institute (API) proficiency testing (PT) reports and interview with the Technical Consultant (Staff A), the laboratory failed to obtain satisfactory PT scores of at least 80% for two consecutive events for the prothrombin time test (analyte 0845) in the Hematology specialty in 2025, resulting in unsuccessful PT performance. Findings include: 1a. Review of 'CASPER Report 0153D', created September 3, 2025, showed this laboratory had unsuccessful performance for prothrombin time testing (analyte 0845). 1b. Review of 'CASPER Report 0155D', created September 4, 2025. showed the laboratory had unsatisfactory performance for prothrombin time testing in events one and two in 2025. Event one, score 0% Event two, score 60% 2a. Review of API 'Performance Summary' reports showed the following scores for prothrombin time testing in 2025: First Event, score 0% Second Event, score 60% 2b. The API 'Performance Summary, 2025 Hematology / Coagulation - 2nd Event' report identified the prothrombin time performance as unsuccessful. 3. During a video call with Staff A on September 17, 2025, at 2:00 PM, Staff A confirmed the laboratory received unsatisfactory scores for prothrombin time testing for two consecutive PT events in 2025 and confirmed the laboratory's prothrombin time PT performance was unsuccessful.
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 review of American Proficiency Institute Proficiency Testing (PT) reports and interview with the Technical Consultant (Staff A), the laboratory failed to obtain satisfactory PT scores for prothrombin time testing in the first and second events in 2025, two consecutive events, resulting in unsuccessful PT performance. The laboratory director did not ensure personnel were reporting PT results promptly and accurately to prevent unsuccessful PT performance. See D6004.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on proficiency testing desk review of American Proficiency Institute (API) Proficiency Testing (PT) reports and interview with the Technical Consultant (Staff A), the laboratory failed to obtain satisfactory PT scores for the prothrombin time test for two consecutive events in 2025, resulting in unsuccessful PT performance. The laboratory director did not ensure personnel reported PT results promptly and accurately to prevent unsuccessful PT performance. Findings include: 1a. Review of the API 'Performance Summary' report for the first hematology and coagulation event in 2025 showed the laboratory received a score of 0% for all tests included in the event, including the prothrombin time test. The report showed the laboratory failed to participate in the event. 1b. Review of the API 'Performance Summary' and 'Comparative Evaluation' reports for the second event in 2025 showed the laboratory received a score of 60% for prothrombin time testing with unacceptable results for samples COA-06 and COA-07. 2. During a video call with Staff A on September 17, 2025, at 2:00 PM, Staff A confirmed testing personnel did not report PT results from the first event in 2025 timely and confirmed testing personnel did not report prothrombin time results accurately in the second event in 2025.