

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0395391	(X3) Date Survey Completed 01/19/2021
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
D2094	<p>ROUTINE CHEMISTRY CFR(s): 493.841(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of American Proficiency Institute (API) Chemistry Core proficiency testing (PT) records and interview with a technical consultant and testing personnel, the laboratory did not evaluate three of three unsatisfactory scores for event two in 2020 to employ the technical assistance necessary to correct problems associated and did not perform remedial action. Findings include: 1. Review of the API Chemistry Core PT event two in 2020 showed the following results: a. Prostate-Specific Antigen (PSA): 0% b. Thyroid Stimulating Hormone (TSH): 40% c. Vitamin B-12: 50% Further review showed no evidence the laboratory evaluated the scores to correct problems associated with the results and did not perform remedial action. 2. Interview with the technical consultant and testing personnel, staff A, on January 19, 2021 at 11:55 AM, confirmed the laboratory did not evaluate three of three unsatisfactory scores for Chemistry Core event two in 2020 to employ the technical assistance necessary to correct the problems associated with the results and did not perform remedial action.</p>
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p>

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on surveyor review of American Proficiency Institute (API) proficiency testing (PT) records and interview with a technical consultant and testing personnel, the laboratory did not evaluate the accuracy for fifty-one of sixty-eight "Educational Blood Cell Identification" proficiency testing results in 2019 and 2020. Findings include: 1. Review of API Hematology PT records showed the laboratory did not evaluate the accuracy for fifty-one of sixty-eight ungraded "Educational Blood Cell Identification" results in 2019 and 2020. 2. Interview with a technical consultant and testing personnel, staff A, on January 19, 2021 at 11:55 AM, confirmed the laboratory did not evaluate the accuracy for fifty-one of sixty-eight "Educational Blood Cell Identification" PT results in 2019 and 2020. This is a repeat deficiency from September 15, 2010.

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 laboratory procedures and interview with the technical consultant and testing personnel, the laboratory director did not approve updates to two of two procedures prior to use. Findings include: 1. Review of the laboratory procedure manual showed the laboratory updated the "Daily Start Up" and "Daily Shut Down" procedures on May 19, 2020. The procedures show no evidence of review or approval by the laboratory director. 2. Interview with the technical consultant and testing personnel, staff A, on January 19, 2021 at 12:15 PM, confirmed the laboratory director did not review or approve two of two procedures prior to use. This is a repeat deficiency from July 27, 2016 and August 30, 2018.