Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0693080	04/16/2025
Name of Provider or Supplier	**Street Address, City, State**	
Uw Stevens Point Student Health	910 Fremont St, Stevens Point, 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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 test verification records for one of one new analyzer and interview with the Laboratory Director, the laboratory did not document the verification of their previous reference ranges for Complete Blood Count (CBC) tests to show they were appropriate for the laboratory's patient population prior to starting patient CBC testing in February 2025 with the Sysmex XN-330 hematology analyzer. Findings include: 1. Review of the verification studies the laboratory completed for the Sysmex XN-330 hematology analyzer showed no evaluation of reference ranges. The laboratory performed correlation studies with another Sysmex analyzer. 2. Interview with the Laboratory Director on April 16, 2025, at 2:15 PM revealed the laboratory continued using reference ranges developed for the Abbott CELL-DYN Emerald hematology analyzer previously used in this laboratory for CBC testing. Further interview confirmed the laboratory did not document evaluation of the appropriateness of using CELL-DYN Emerald reference ranges with the Sysmex XN-330 prior to reporting patient results.