Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D1040142	04/07/2021
Name of Provider or Supplier	**Street Address, City, State**	
Oconto Hospital And Medical Center	820 Arbutus Ave, Oconto, 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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) 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 proficiency testing (PT) records and interview with the technical supervisor, the laboratory did not verify the accuracy of ungraded hematology PT results in 2020 and 2021, Findings include: 1. Review of PT reports for the first event in 2021 showed the laboratory reported blood cell identification BCP-10 as a reactive lymphocyte. The target result was a blast cell. The records showed no evidence of review. The third event in 2020 included cell BCP-27 reported as hypogranular platelet. The target was normal platelet. The records showed no evidence of review. The PT program did not grade results for Large Unclassified Cells for the first, second, and third events in 2020 and the records showed no evidence the laboratory reviewed the results. 2. Interview with the technical supervisor on April 7, 2021 at 9:35 AM confirmed the laboratory had not verified the accuracy of hematology analytes that the PT program did not grade.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the

	laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Individualized Quality Control Plan (IQCP) developed by the laboratory and interview with the technical consultant, the laboratory did not establish the number, type, and frequency of testing of control materials for the Siemens epoc blood analysis system. Findings include: 1. Review of the laboratory's IQCP for the epoc blood analyzer, signed on August 30, 2020, shows the only reference to the number type and frequency of testing of control material is the following statement, "Manufacturer requires that from each lot in each shipment of cards, at least two (2) levels of fluid controls in duplicate must be analyzed. Per CAP point of care requirements QC will be run at least every 30 days." 2. Interview with the technical consultant on April 7, 2021 at 1:30 PM confirmed the IQCP did not specify the laboratory's requirements for control testing, including the specific levels and identification of the control material used on the epoc blood analyzer.