Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2215576	02/21/2024
Name of Provider or Supplier	**Street Address, City, State**	
Aspirus Wausau Hospital	333 Pine Ridge Blvd, Wausau, 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
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor review of patient test reports and interview with a Technical Consultant (Staff A), two of two test reports reviewed did not indicate the name and address of the laboratory location where personnel performed the testing. Findings include: 1. Review of a test report in the electronic medical record (EMR) from a patient with testing on the iSTAT analyzer and a second report from a patient with ACT (Activated Clotting Time) showed the location of testing as Aspirus Reference Laboratory, CLIA number 52D0395330. 2. Interview with Staff A on February 21, 2024, at 3:00 PM confirmed testing personnel performed the testing for the two reviewed patients at the Aspirus Wausau Hospital, CLIA number 52D2215576, and confirmed the testing location in the EMR was incorrect.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

	This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and control logs and interview with a Technical Consultant (staff A), testing personnel did not document quality control testing as required by the laboratory's quality control policies on four of four AVOXimeter analyzers used for patient testing. Additionally, testing personnel did not document changes in lot number of cuvettes used for two of the four analyzers. Findings include: 1. Review of the procedure, 'AVOXimeter Quality Control Testing', showed the laboratory required weekly quality control (QC) with two levels of liquid controls. Review of the 'Oxyhemoglobin Measurement Using the Avoximeter 1000(E) (Awh)' procedure showed testing personnel were directed to enter quality control results on the Quality Control Log. 2. Review of 'AVOXimeter Quality Control Log' records from the four AVOXimeter analyzers (2880, 2882, 2883, 2942) from November 2023 through January 2024 showed the laboratory did not document QC performance during the weeks listed below: Date range: Analyzers without liquid QC during the week November 26 - December 2: 2880 / 2882 / 2883 / 2942 December 3 - 9: 2882 December 24 - 30: 2880 / 2883 December 31 - January 6: 2880 / 2882 / 2883 / 2942 January 14-20: 2882 Additional review of the logs for analyzer 2882 showed testing personnel used cuvette lot number 8041555 from November through January. The logs showed the pathlength of the cuvettes in November and December was 110 and the pathlength changed in January to 114. The logs for analyzer 2883 showed cuvette lot 819389 was in use from November through January 4 when testing personnel entered a new pathlength for lot 8169272. The December log showed a path length change on December 8, 2023. Testing personnel did not record the cuvette lot number in use from December 8 through January 3 on the December or January logs. 3. Interview with Staff A on February 21, 2024, at 2:30 PM confirmed testing personnel did not document the weekly quality control results as required.