Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0676856	02/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Aspirus Wausau Hospital	215 N 28th Ave, 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
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on surveyor review of chemistry maintenance records and interview with the Technical Consultant the laboratory has not consistently documented required maintenance. Findings include: 1. Review of maintenance records in 2016 and 2017 shows required maintenance is not consistently being documented on the Chemistry Maintenance Log. September 2016: Weekly maintenance for "Clean Probes and Splash Guard" was documented 3 out of 4 times that month. Weekly maintenance for "Clean ISE Tower" was documented 2 out of 4 times that month. October 2017: Weekly maintenance for "Clean Probes and Splash Guard" and "Clean ISE Tower" was documented 3 out of 4 times that month. Weekly maintenance for "Backup Database" was performed 2 out of 4 times that month. Monthly "Clean Waste Box Fitting" was not documented as having been performed. November 2017: Weekly maintenance for "Clean Probes and Splash Guard" was documented 3 out of 4 times that month. Weekly maintenance for "Clean ISE Tower" was documented 2 out of 4 times that month. 2. Interview with the Technical Consultant on February 13, 2018 at 2:30 PM confirms testing personnel did not document chemistry maintenance as required.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's

	verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of quality control and test system records on the Cobas Integra 400 chemistry analyzer and interviews with the Technical Consultant and Testing Personnel, the laboratory has not documented corrective actions taken when the test system is not performing as expected. Findings include: 1. Review of test system records from the Cobas Integra 400 chemistry analyzer shows an "ISE Unstable" error on June 15, 2016. Corrective action to resolve the problem was not documented on the chemistry corrective action log or in the Unity Quality Control (QC) software program. 2. Sodium (Na), Potassium (K), and Chloride (CL) analytes had "R1(2S)" QC warnings on August 7, 8, and 16, 2016 and November 29 and 30, 2016. No corrective action was documented on a corrective action log or the Unity QC software program. 3. Calcium analyte had "R1(2S)" QC warnings on April 4 and 5, 2017. No corrective action was documented on a corrective action log or the Unity QC software program. 4. Interview with the Technical Consultant and Testing Personnel on February 13, 2018 at 2:45 PM confirms corrective actions have not been documented in the chemistry testing area when the test system is not performing as expected.