Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0041151	04/09/2026
Name of Provider or Supplier	**Street Address, City, State**	
Appleton Area Health	30 South Behl Street, Appleton, MN	

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
D0000	The Appleton Area Health laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey completed on April 9, 2026. The following standard-level deficiencies were cited: 493.1253 Establishment and verification of performance specifications 493.1256 Control procedures 493.1291 Test report .
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 observation, document review, and interview with laboratory personnel, the laboratory failed to complete one of five required Performance Verification (PV) activities for one of five newly implemented Chemistry analytes prior to reporting patient test results in 2025. Findings are as follows: 1. The laboratory performed Venous Blood Gas (VBG) testing under the Chemistry specialty as confirmed by the General Supervisor (GS) during a tour of the laboratory at 12:30 p.m. on 4/8/26. 2. A Siemens EPOC Blood Gas Analysis device was observed as present and available for use VBG testing on patient samples during the tour. The laboratory implemented VBG testing using the EPOC device for the following analytes on 7/28/25. pH, Venous PCO2, Venous PO2, Venous Base Excess, Venous Bicarbonate, Venous 3. PV documentation found in the New Test Implementation 2024 + 2025 binder

	provided by the laboratory included accuracy, precision, and linearity verification data for all analytes. Reference range verification documentation was not found for PO2. 4. In an interview at 1:58 p.m. on 4/9/26, the GS confirmed the above findings and indicated the laboratory performed 14 VBG tests on patient samples in 2025. .
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to evaluate stain for intended reactivity each day of use for one of ten days of patient testing in August 2024. Findings are as follows: 1. The laboratory performed manual differential blood smear testing under the specialty of Hematology as confirmed by the General Supervisor (GS) during a tour of the laboratory at 12:30 p.m. on 4/8/26. 2. Easy III Quick Stain reagents and an Olympus CH30 microscope used to perform manual differentials were observed as present and available for use during the tour. 3. Testing personnel were required to perform and document stain quality and initial a Daily Maintenance Log each day of patient testing as defined in the Easy III Quick Stain For Hematology procedure found in the Hematology & Coagulation Procedure Manual provided by the laboratory on the date of survey. 4. Hematology manual differential smear testing was performed on a single patient sample on 8/3/24, reviewed on the date of survey. Documentation of acceptable stain reactivity was not found for this day of patient testing. The laboratory was unable to provide the missing documentation upon request. 5. In an interview at 11:15 a.m. on 4 /9/26, the GS confirmed the above findings and stated the laboratory did not document stain quality on the day the patient test was performed. .
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with the laboratory personnel, the laboratory failed to ensure one of five pertinent Chemistry reference intervals were included on a patient test report in 2025. Findings are as follows: 1. A Siemens EPOC Blood Analysis device was observed as present and available for use for Venous Blood Gas (VBG) testing on patient samples under the Chemistry specialty as confirmed by the General Supervisor (GS) during a tour of the laboratory at 12:30 p.m. on 4/8/26. 2. A reference interval for PO2 was not included on a patient test report from 10/31/25 reviewed on the date of survey. See below: Patient Test Report from 10/31/25 Analyte Reference Interval pH, Venous 7.32 - 7.45 pH PCO2, Venous 38.0 - 48.0 mm Hg PO2, Venous ---- Base Excess, Venous -2.0 - 3.0 mmol/L Bicarbonate, Venous 22.0 - 29.0 mmol/L 3. A reference interval for PO2 was not established in the Performance Verification activites performed prior to

	implementation of the EPOC device. See D5421. 4. In an interview at 1:58 p.m. on 4/9 /26, the GS confirmed the above findings and indicated the laboratory performed 14 VBG tests on patient samples since implementing the EPOC Blood Gas Analysis device on 7/28/25. .