Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0041151	06/22/2022
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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure one of one Individualized Quality Control Plans (IQCP) developed in 2020 was approved, signed, and dated by the laboratory director prior to implementation. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by Technical Consultant (TC) during a tour of the laboratory at 8: 10 a.m. on 06/22/22. 2. An Cepheid GeneXpert was observed as present and available for use during the tour of the laboratory. The laboratory performed the SARS-CoV-2, Flu A, Flu B and RSV Combination Test (4-Plex) with this analyzer beginning in December 2020 as indicated in the 4-Plex performance verification documentation and confirmed by the TC during the tour. 3. An IQCP dated 11/20/20 was found in laboratory records. 4. The laboratory director's approval signature and date were not included in the IQCP document. 5. The laboratory provided approximately 1100 Microbiology results to patients annually as indicated on the Form CMS-116 provided by the laboratory on date of survey, 06/22/22. 6. In an interview at 12:15 p.m. on 06/22 /22, the TC confirmed the above finding. .
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2)

	Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform and document calibrations with the frequency indicated in procedure and established by the manufacturer for one of one new Chemistry analyte implemented in 2021 . Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory on at 8:10 a.m. on 06/22/22. 2. An Alfa Wassermann ACE Axcel Chemistry analyzer was observed as present and available for use during the tour of the laboratory. The laboratory implemented Phosphorous (PHOS) testing on this analyzer in August 2021 as indicated in the PHOS performance verification (PV) records. The Laboratory Director approved the PV on 08/16/21. 3. The Alfa Wassermann Ace Inorganic Phosphorus procedure, located in the Ongoing New Assays - Starting Dec 2020 manual, established PHOS calibration performance frequency as every 20 days. The manufacturer's package insert indicated PHOS calibration was required every 20 days. 4. The laboratory failed to perform PHOS calibration every 20 days from September 2021 through date of survey, 06/22/22. Laboratory records from September through November 2021 indicated PHOS calibration was performed every 30 days. Testing Personnel TP5 indicated the analyzer software for PHOS calibration was set at every 30 days. 5. In an interview at 3:45 p.m. on 06/22/22, the TC confirmed the above finding. 6. In an email received at 9:49 a.m. on 06/23/22, the TC indicated 9 patient specimens received PHOS testing from testing implementation to date of survey, 06/22/22. .
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform and document alarm system function checks for the blood storage refrigerator in 2021 with the frequency defined by the laboratory. Findings are as follows: 1. The laboratory performed Immunohematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory on at 8:10 a.m. on 06/22/22. 2. The laboratory stored blood products in a designated refrigerator. The blood storage refrigerator had a temperature alarm system. 3. Monthly, quarterly, weekend, and holiday blood product storage alarm check requirements were established on the Blood Bank temperature log. The alarm check requirements were listed as follows: Monthly - during a day shift Quarterly - during a night shift in

	March, June, September, and December Weekend - first weekend in January Holiday - Labor Day 4. Blood product storage alarm checks were not performed on seven of eighteen required occasions in 2021 as indicated on the Blood Bank temperature log. See below. February Monthly March Quarterly July Monthly September Monthly, Quarterly December Monthly, Quarterly 5. The laboratory provided approximately 100 Immunohematology results to patients annually as indicated on the Form CMS-116 provided by the laboratory on date of survey, 06/22/22. 6. In an interview at 5:00 p.m. on 06/22/22, the TC confirmed the above finding. .
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory director failed to ensure initial training on two new analyzers was documented for four of nine testing personnel in 2020 and one of seven testing personnel in 2021. Findings are as follows: 1. The laboratory performed Microbiology and Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 8:10 a.m. on 06/22/22. 2. The laboratory implemented testing on two new analyzers, the Cepheid GeneXpert System in December 2020 and the Beckman Coulter DxH 520 Hematology analyzer in December 2021, as indicated in laboratory records. 3. Training documents for the two new analyzers were not found during review of personnel records for the following testing personnel (TP): GeneXpert TP1 TP2 TP4 TP5 DxH 520 TP4 The laboratory was unable to provide the missing training documents upon request. 4. The laboratory provided approximately 1100 Microbiology results and approximately 10,000 Hematology results to patients annually as indicated on the Form CMS-116 provided by the laboratory on date of survey, 06/22/22. 5. In an interview at 12:10 p.m. on 06/22/22, the TC confirmed the above finding.