Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0393832	07/01/2026
Name of Provider or Supplier	**Street Address, City, State**	
Gundersen Boscobel Area Hospital And Clinics	205 Parker St, Boscobel, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory policies, competence assessment records, and the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report (Form 209), and interview with the Ancillary Services Manager (Staff A), the laboratory did not follow their procedures for competence assessment for three of four staff members identified as technical consultants (TC), technical supervisors (TS) or general supervisors (GS). 1. Review of the Technical Consultant or Technical Supervisor and General Supervisor sections of the policy, "Objectives and Organization - Pathology and Laboratory Medicine, Lab - 0175", showed "Competency will be assessed annually using the form Technical Consultant / Technical Supervisor / General Supervisor Assessment, Lab-0135.18". 2. Review of competence assessment records revealed the director completed an assessment of Staff A in their performance of the responsibilities delegated as a TC, TS, and GS and signed the assessment on January 26, 2026. No other records were available for evaluation of other personnel with these delegated responsibilities including Staff B, C and D. 3. Review of the CMS Form 209 submitted for this survey showed the director delegated: Staff B with GS responsibilities for high complexity testing, TC responsibilities in bacteriology, mycology, parasitology, immunology, chemistry, and hematology and TS responsibilities in bacteriology and hematology. Staff C with TC and TS responsibilities in immunohematology, and Staff D with TC responsibilities in Chemistry. 4. Interview with Staff A on June 30, 2026, at 12:45 PM confirmed the director did not complete annual competence assessments for each of the staff members assigned TC, TS, and GS responsibilities.

D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures, proficiency testing (PT) and other laboratory records, and interview with the Ancillary Services Manager (Staff A), the laboratory did not perform twice annual accuracy evaluations for fluid white blood cell (WBC) differentials in two of the last two years. Findings include: 1. Review of the procedure, 'Body Fluid Analysis - Affiliate, Lab - 8760' showed in the section, 'Differentials done on site (Boscobel and St. Joseph's)', "If WBC count is >200, prepare slide for differential. Stain and count per manual differential procedure if a differential is requested to be performed on site." 2. Review of PT records from 2024 through 2026 showed no results for fluid differentials. 3. Review of laboratory records from 2025 through 2026 showed no evidence the laboratory used an alternate method to evaluate fluid differential accuracy. 4. Interview with Staff A on June 30, 2026, at 2:05 PM confirmed the laboratory would perform a fluid differential when the WBC count was greater than 200 and confirmed the laboratory did not verify the accuracy of the fluid differential procedure twice annually.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (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: Item 1: Based on surveyor review of laboratory records and procedures and interview with the Ancillary Services Manager (Staff A), the laboratory director did not approve, sign, and date one of one new procedure for performing High Sensitivity Troponin I test on the i-STAT analyzer before the laboratory placed the testing into use. Findings include: 1. Review of the performance verification records for the High Sensitivity Troponin I test on the i-STAT showed the laboratory implemented the test on November 18, 2025. 2. Review of the procedure, 'High Sensitivity Troponin I using the Abbott i-STAT, Lab-8650', origination date March 24, 2026, showed the laboratory director approved the procedure on March 23, 2026. There was no evidence the laboratory had an earlier version of the procedure. 3. Interview with Staff A on July 1, 2026, at 12:30 PM confirmed the implementation date and procedure approval date, and confirmed the laboratory director failed to approve, sign, and date the new procedure before the laboratory placed the test into use. Item 2: Based on surveyor review of laboratory procedures and interview with the Ancillary Services Manager (Staff A), the laboratory director did not approve, sign, and date one of one procedure for transfusion reactions when the laboratory changed its procedure. Findings include: 1. Review of 'Transfusion Reactions, Lab-3508' showed the laboratory revised the policy February 21, 2025. Further review showed the laboratory director approved an older version of the policy on November 8, 2023. 2. Interview with Staff A on June 30, 2026, at 2:50 PM confirmed the laboratory director did not approve, sign, and date the changes in the procedure.

D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) (e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and procedures and interview with the Ancillary Services Manager (Staff A) the laboratory did not document the date of initial use on the procedure for one of one new test system placed into use. Findings include: 1. Review of the performance verification records for the High Sensitivity Troponin I test on the i-STAT showed the laboratory implemented the test on November 18, 2025. 2. Review of the procedure, 'High Sensitivity Troponin I using the Abbott i-STAT, Lab-8650', showed no indication of the initial date of use for the test at this laboratory. 3. Interview with Staff A on July 1, 2026, at 12:30 PM confirmed the laboratory implemented the test on November 18, 2025 and confirmed the procedure did not include the initial date of use for the i-STAT High Sensitivity Troponin I test at this laboratory.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation of a phlebotomy collection tray and interview with the Ancillary Services Manager (Staff A), one out of 52 blood sample collection tubes on a phlebotomist's collection tray was expired but available for use. Findings include: 1. Observation of a phlebotomy collection tray on July 1, 2026, at 10:30 AM revealed a red top vacutainer blood sample collection tube with expiration date June 3, 2026, available for use. 2. Interview with Staff A on July 1, 2026, at 1:50 PM confirmed the blood sample collection tube was expired and could have been used for collection.
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. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory's individualized quality control plans

	(IQCPs) and interview with the Ancillary Services Manager (Staff A), three of four of the laboratory's IQCPs did not specify the type of controls used. Findings include: 1a. Review of two IQCPs, 'Quality Control Plan Test: MEDTOX Urine Drug Screen' and 'Quality Control Plan Test: Serum Pregnancy (Sure-Vue)', revealed both stated, "Perform two levels of external quality control (one positive and one negative), upon receipt of a new lot number of test kits/shipment and with every 30 days of kit use." Further review showed the IQCPs did not define the type of positive and negative external controls required. 1b. Review of the IQCP, 'Quality Control Plan Test: i-STAT Blood Gases, Creatinine, Chem 8+, HS Troponin I', revealed the plan stated, "Perform two levels of external quality control (Level 1 & 3), upon receipt of a new shipment, new lot number of test kits, and with every 30 days of kit use." Further review showed the IQCP did not define the type of external controls required. 2. Interview with Staff A on July 1, 2026, at 12:20 PM confirmed the IQCPs did not identify the type of external quality controls required for each of the test systems.
D6080	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the Ancillary Services Manager (Staff A), the laboratory director was not on site in the last six months. Two of two documented visits occurred on or before October 13, 2025. Findings include: 1. Review of records documenting onsite visits by the laboratory director showed they performed director responsibilities during two onsite visits to the laboratory in 2025 on April 14 and October 13. The laboratory had no documentation showing the director made an onsite visit after October 13, 2025. 2. Interview with Staff A on July 1, 2026, at 1:20 PM confirmed the director had not been onsite in the last six months.
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) (e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and This STANDARD is not met as evidenced by: Based on surveyor review of humidity records and maintenance logs and interview with the Ancillary Services Manager (Staff A), the director did not ensure the environmental conditions of the laboratory were appropriate for testing performed on the ACL Top coagulation analyzer during three of three months reviewed in 2026. Findings include: 1. Review of the maintenance log, 'ACL TOP 350 Model Maintenance Log' from January 2026 showed personnel noted issues with HemosIL RecombiPlasTin reagent stability and contacted the manufacturer. Personnel noted the laboratory installed a humidifier to address the issue. 2. Review of communication

	from Werfen, the manufacturer of the HemosIL RecombiPlasTin reagent, showed the manufacturer recommended maintaining relative humidity levels from 30% to 60% and stated, "In cases where these conditions cannot be maintained, Werfen recommends that reagents be stoppered and capped in their original vial and stored at 2-8 degrees C (Celsius) when not in use in order to optimize reagent stability". 3. Review of humidity records documented on the 'Daily Temperature Monitoring Log' from February through April 2026 showed the following: Month | number of days humidity measured less than 30% | number of days in the month February | 25 | 28 March | 20 | 31 April | 14 | 30 The log showed the laboratory's acceptable humidity range was less than 80%. 4. Interview with Staff A on July 1, 2026, at 10:30 AM confirmed the environmental conditions identified as appropriate for testing by the manufacturer of the coagulation reagents used on the ACL Top coagulation analyzer were not met after personnel installed the humidifier in the laboratory. Further interview confirmed personnel did not stopper and cap reagents when they were not in use during periods of low humidity.