Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0393832	08/09/2018
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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and documents, and interview with the technical consultant, the procedure for transfusion reaction investigations does not reflect the process used in the laboratory. Findings include: 1. Review of the "Transfusion Reactions" procedure index number "Lab-3508" states that transfusion reaction investigations which include Direct Antiglobulin Testing (DAT) are applicable to "Boscobel Area Hospital laboratories." 2. Review of the "Transfusion Reaction Investigation" form "Lab-3508.2" states "Perform IgG DAT at local hospital. Send sample to GHS La Crosse or your blood center for C3 testing." 3.

	Review of lab procedures show that DAT testing was discontinued when the lab started immunohematology testing using the Ortho MTS Gel system on December 28, 2017. 4. Interview with the technical consultant on August 9, 2018 at 10:15 AM confirmed that the lab does not perform IgG DAT testing and that the procedure for transfusion reaction investigations does not reflect the process used in the laboratory.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory quality control records and procedures, and interview with the laboratory technical consultant the laboratory does not use an elevated serum bilirubin control for monitoring the abnormal range of neonatal bilirubin testing. Findings include: 1. Review of the laboratory procedure "Quality Control Criteria for Chemistry" index number "Lab-4405" states "Total and direct bilirubin will also be tested with an elevated bilirubin control as needed." 2. Review of laboratory quality control (QC) records for the bilirubin assay show that two levels of QC are performed on a daily basis. The QC records for the bilirubin assay show that an elevated serum based bilirubin control for monitoring the abnormal range of neonatal bilirubin's is not assayed when performing neonatal bilirubin testing. 3. Interview with the technical consultant on August 9, 2018 at 11:15 AM confirms that an elevated serum based bilirubin control is not used to monitor the abnormal range of neonatal bilirubin's.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of quality control records, the Individualized Quality Control Plan (IQCP), and interview with the technical consultant, the laboratory has not performed the required quality control testing for media that had previously been recognized as exempt by the Clinical and Laboratory Standards Institute (CLSI). Findings include: 1. Review of the approved IQCP for "Microbiology Media" states: "External Controls--Perform two levels of control materials (positive and negative) for the following: -Upon receipt of a new shipment and/or lot number of media. -According to specific policy for each media type." etc. The IQCP does not specify which media in the lab requires external quality control testing and it does not specify

	the quality control requirements for media that had previously been recognized as exempt media. 2. During the interview with microbiology Testing Personnel A on August 8, 2018 at 1:30 PM it was stated that no media quality control (QC) is performed except for chocolate agar QC. 3. Review of quality control records for media types previously recognized as exempt shows the laboratory has not checked each batch for its ability to support growth, select or inhibit specific organisms, or produce expected biochemical reactions. 4. Interview with the technical consultant on August 8, 2018 at 2:00 PM confirmed the laboratory has not performed the required quality control testing on microbiology media that was previously recognized as exempt and that these media types are not present in the Microbiology Media IQCP Quality Control Plan.