Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0393832	01/05/2021
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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on surveyor review of immunoassay calibration verification records and procedures from the Roche Elecsys 411 analyzer and interview with general supervisor, the laboratory did not perform calibration verification analysis that included the maximum reportable range for the Free Thyroxine (FT4) analyte in 2019 and 2020. Findings include: 1. Review of calibration verification records for the Roche Elecsys 411 analyzer showed the laboratory performed calibration verification

	for FT4 with a range of less than 0.101-4.71 ng/dL. 2. Review of the FT4 procedure for the Roche Elecsys 411 analyzer showed the laboratory's reportable range is 0.1-7.77 ng/dL. 3. Interview with the general supervisor on January 5, 2021 at 9:15 AM, confirmed the laboratory did not perform calibration verification analysis that included the maximum reportable range for the FT4 analyte in 2019 and 2020.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Individualized Quality Control Plan (IQCP) and control and patient test records, and interview with the general supervisor, the laboratory did not meet their stated Quality Control (QC) requirements for testing external controls every thirty days for the serum human chorionic gonadotropin (HCG) analyte for two of twelve months in 2020. Findings include: 1. Review of the laboratory's IQCP for serum HCG testing showed external QC is required every thirty days and with each new lot or shipment of test kits. 2. Review of QC records showed the laboratory performed QC testing on: a. March 4, 2020 and April 19, 2020, with thirty day QC due April 4, 2020. b. November 13, 2020 and December 27, 2020, with thirty day QC due December 13, 2020. 3. Review of patient test records showed the laboratory ran patient 1 on April 12, 2020, with no QC run within thirty days prior to patient testing. Further review of patient test records showed the laboratory ran patient 2 on December 15, 2020 and patient 3 on December 21, 2020, with no QC run within thrity days prior to patient testing. 4. Interview with the general supervisor on January 4, 2021 at 12:45 PM confirmed the laboratory did not meet their QC requirements for serum HCG testing for two of twelve months in 2020.