Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0385651	12/16/2020
Name of Provider or Supplier	**Street Address, City, State**	
Horn Memorial Hospital	701 East Second Street, Ida Grove, IA	

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 review of Ortho Vitros calibration records, lack of calibration verification records and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 10:20 am on 12/16/2020, the laboratory failed to perform calibration verification every six months for one out of one time period for the analytes, vitamin D and vitamin B12, from 04/15/2020- 12/16/2020. The findings include: 1. The laboratory began using an Ortho Vitros XT 7600 chemistry analyzer

	on 04/15/2020. 2. At the time of the survey, personnel identifier #3 confirmed that the laboratory did not perform calibration verification for the analytes, vitamin D and vitamin B12, during the time period between 04/15/2020 and 12/16/2020.