

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0396797	<b>(X3) Date Survey Completed</b>  10/28/2020
<b>Name of Provider or Supplier</b>  Adventhealth Durand	<b>Street Address, City, State</b>  1220 3rd Ave West, Durand, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5439</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> CFR(s): 493.1255(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of immunoassay calibration verification records from the Roche Elecsys 411 analyzer and interview with the technical consultant, the laboratory did not perform calibration verification analysis that included the minimum and maximum reportable range for five of five analytes. Finding include: 1. Review of calibration verification records on the Roche Elecsys 411 analyzer showed the laboratory did not perform calibration verifications consistent with the reportable</p>

range for Beta-Human Chorionic Gonadatropin (BHCG), Procalcitonin (PCT), Brain Natriuretic Peptide (BNP), Troponin-T High Sensitive (TnT-hs) and Vitamin D (25-OH) analytes: Test:Calibration Range:Reportable Range BHCG:4.84-8070mIU/mL: 0.1-10000mIU/mL PCT:0.5-81ng/mL:0.02-100ng/mL BNP:136-2557ng/L:5-35000ng /L TnT-hs:13.54-7140ng/L:6-10000ng/L 25-OH:18.89-79.73ng/mL:5-100ng/mL 2. Interview with the technical consultant on October 27, 2020 at 3:30 PM confirmed the calibration verification range did not cover the reportable range for five of five analytes.

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:  
Based on surveyor review of frozen section reports and interview with the technical consultant, the preliminary frozen section report did not include all patient information for two of two patients reviewed for 2019 and 2020. Findings include: 1. Review of Patient one and Patient two showed the preliminary frozen section reports have a space to include the time results were reported to the surgeon and the report did not include the time the preliminary results were reported. Further review of Patient two showed the preliminary frozen section report did not include the date of specimen collection. 2. Interview with the technical consultant on October 28, 2020 at 11:03 AM, confirmed the preliminary frozen section reports for Patient one and Patient two do not have all the report information present.