

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  02D1002123	<b>(X3) Date Survey Completed</b>  12/07/2022
<b>Name of Provider or Supplier</b>  Avante Medical Center	<b>Street Address, City, State</b>  915 West Northern Lights Blvd, Anchorage, AK	
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>CALIBRATION AND CALIBRATION VERIFICATION 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 record review and interview with the laboratory director, the laboratory did not verify the reportable range of the chemistry tests in those instances where the calibration verification material did not extend to the entire analytical measurement range of the Alfa Wasserman Ace Axcel chemistry analyzer. Findings include: 1. The calibration verifications using Audit MicroControls did not extend to the full analytical measurement range for alkaline phosphatase, calcium, cholesterol, sodium,</p>

total protein, and triglyceride. 2. In an interview on 12/7/22 at 12:30 PM the laboratory director confirmed the laboratory's reportable ranges were not adjusted to the limits determined by the calibration verification. 3. The laboratory reported 20,900 chemistry tests annually on the CMS-116 dated 12/7/2022.