

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D1053182	<b>(X3) Date Survey Completed</b> 01/25/2023
<b>Name of Provider or Supplier</b> Vascular Access Services (Va Beach Endovascular)	<b>Street Address, City, State</b> 397 Little Neck Road, Virginia Beach, VA	
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>D0000</b>	An announced CLIA recertification survey was conducted at Vascular Access Services (Virginia Beach Endovascular) on January 25, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited is as follows:
<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:</p>

Based on a review of procedures, calibration verification records for the facility's Abbott iSTAT point of care chemistry analyzer, lack of documentation, and an interview, the laboratory failed to follow their six (6) month calibration verification protocol for eight (8) of 8 chemistry analytes in calendar years 2021 and 2022. Findings include: 1. Review of procedures revealed a policy to perform iSTAT calibration verification once every six months. 2. Review of the laboratory's 2021 and 2022 calibration verification records for Sodium (Na), Potassium (K), Chloride (Cl), TCO<sub>2</sub>, Ionized Calcium (iCa), Glucose (Glu), Urea Nitrogen (BUN)/Urea, and Creatinine (Creat) reported on the iSTAT analyzer (Serial Number 368216), revealed the following two records: 07/13/21 Calibration Validation study to establish reportable range performed and accepted by testing personnel (TP) and lab director (LD); 12/07/22 Calibration Verification performed and accepted by TP and LD. The inspector requested to review additional documentation of calibration verification for Na, K, Cl, TCO<sub>2</sub>, iCa, Glu, BUN, and Creat on the iSTAT performed in 2021 and 2022. No additional documentation was available for review. The charge nurse stated on 1/25/23 at approximately 11:30 AM, "We missed doing the every six month verifications because some times it was hard to get our reagents". 3. An exit interview with the charge nurse on 1/26/23 at approximately 12:30 PM confirmed the above findings.