

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  49D1053182	<b>(X3) Date Survey Completed</b>  09/11/2023
<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>	<p>An off-site CLIA proficiency test desk review was conducted for Vascular Access Services (Virginia Beach Endovascular) on September 7, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The desk review also included interviews with proficiency testing vendor representative, director of operations, and lead laboratory coordinator on 9/7/23, 9/8/23, and 9/11/23 respectively. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:</p>
<b>D2093</b>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services (CMS) ASPEN 116 database, off-site proficiency testing (PT) desk review of the facility's 2023 PT documentation, and interviews, the laboratory failed to ensure Abbott iSTAT Chem 8 cartridge analytes Sodium (Na), Potassium (K), Chloride (CL), Glucose (GLU), and Urea Nitrogen (BUN) PT results were returned to College of American Pathologists (CAP) for one (1) of two (2) events reviewed for calendar year 2023. Findings include: 1. Review of the laboratory's CMS ASPEN 116 database for PT scores revealed the following analytes as reported with failed scores: Na, K, CL, GLU, and BUN for 2023 Event 2. 2. Review of the laboratory's CAP 2023 PT documentation (Events 1, 2) revealed that the laboratory failed to submit and received failure to participate scores for 2023 Event 2 for five (5) of 5 analytes: 2023 Critical Care iSTAT Chemistry Event 2 (AQI-B) 0% scores for Na, K, CL, GLU, and BUN. 3. An interview with CAP customer service representative on 9/7/23 at 1 PM revealed that the laboratory failed to submit results for 2023 Event B. An interview with facility's</p>

laboratory coordinator and director of operations on 9/8/23 at 12 noon revealed that the laboratory had contacted CAP and ordered replacement PT challenges for 2023 Event 2 outlined above. 4. An interview with the facility's laboratory coordinator and director of operations on 9/11/23 at 11:30 AM confirmed the above findings.

**D6015**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on a review of Centers for Medicare and Medicaid Services (CMS) CASPER 0096D report, proficiency testing (PT) records, and interviews, the laboratory director (LD) failed to ensure proper enrollment for five (5) of 5 nonwaived chemistry analytes Sodium (Na), Potassium (K), Chloride (CL), Glucose (GLU), and Urea Nitrogen (BUN) performed on the Abbott iSTAT analyzer for four (4) of 5 PT events reviewed for calendar years 2022 and 2023. Findings include: 1. A PT desk review of the laboratory's CASPER 0096D summary report revealed no reported PT scores for routine nonwaived regulated chemistry analytes Na, K, CL, GLU, and BUN for 2022 Events 1-3 and 2023 Event 1. The inspector noted that the CASPER 0096D reported 2023 Event 2 scores as Na 0%, K 0%, CL 0%, GLU 0%, BUN 0%. 2. Review of the laboratory's College of American Pathologists (CAP) PT submission records and results revealed that the laboratory submitted results under waived status for the 5 nonwaived analytes outlined above on the following events: 2022 Critical Care iSTAT Chemistry Event 1 (AQI-A); 2022 Critical Care iSTAT Chemistry Event 2 (AQI-B); 2022 Critical Care iSTAT Chemistry Event 3 (AQI-C); 2023 Critical Care iSTAT Chemistry Event 1 (AQI-A). The inspector inquired regarding the zero scored results for 2023 Critical Care iSTAT Chemistry Event 2 (AQI-B). The director of operations stated on 9/8/23 at 11 AM, "We did not receive the second kit due to a shipping problem and we contacted CAP. They sent us replacement PT samples. We will contact CAP to correct reporting code from waived to nonwaived. We were unaware CAP had changed anything regarding how to enter result codes." 3. An interview with the facility's laboratory coordinator and director of operations on 9/11/23 at 11:30 AM confirmed the above findings.