Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1053182	02/23/2021
Name of Provider or Supplier	**Street Address, City, State**	
Vascular Access Services (Va Beach Endovascular)	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced CLIA recertification survey was conducted at Vascular Access Services (Virginia Beach Endovascular) on February 23, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The survey included entrance interview on 02/11/2021 with initial virtual record review on 02/18/21. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The laboratory was not in compliance with the following Condition under 42 CFR part 493 CLIA Regulations: D6000- 42 CFR. 493.1403 Condition: Moderate Complexity Laboratory Director. Specific deficiencies cited are as follows.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records and an interview, the laboratory failed to document evaluation of results and corrective action for five (5) of 5 unacceptable Urea Nitrogen results on their College of American Pathologists (CAP) PT AQI-B chemistry module in 2020. *REPEAT DEFICIENCY Findings include: 1. Review of the laboratory's 2020 CAP Critical Care Aqueous Chemistry module proficiency documentation, a total of three (3) events, revealed no evidence of review or remedial action for the following 5 unacceptable Urea Nitrogen Abbott iSTAT analyte challenges: 2020 AQI Event B AQI-06 resulted as 12.0 (acceptable range 3.5-5.0); AQI-07 resulted as 96.0 (acceptable range 31.0 - 37.3); AQI-08 resulted as 11.0 (acceptable range 3.4 - 4.9); AQI-09 resulted as 9.0 (acceptable range 2.7 0 4.2); AQI-10 resulted as 11.0 (acceptable range 3.3 - 4.8); resulting in an unsatisfactory score of 0% for Urea Nitrogen. 2. Review of the laboratory's corrective action forms revealed no corrective or remedial action documentation for the analyte challenges listed above. 3. In an exit interview with the laboratory clinical coordinator, on 02/23/21 at approximately 4:30 PM, the above findings were confirmed.

D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of laboratory equipment, a tour, review of manufacturer's package instructions, and interviews, the laboratory failed to follow Abbott iSTAT Activated Clotting Time (ACT) reagent cartridge storage requirements for one (1) test cartridge on the date of the on-site inspection, February 23, 2021. Findings include: 1. In an entrance interview with the laboratory's clinical coordinator on 02/11/21, the inspector noted that the laboratory utilized an Abbott iSTAT analyzer (Serial Number SN 368216) for point of care chemistry/hematology testing during the twenty-four (24) months reviewed. 2. During a tour of the laboratory on 02/23/21 at approximately 3: 00 PM, the inspector noted an ACT iSTAT reagent cartridge stored at room temperature on the testing counter beside the analyzer. The ACT cartridge package (Lot Number R2041) had not been labeled with a room temperature storage expiration date. 3. Review of the iSTAT outer package revealed storage temperature instructions of 2-8 C or 18-30 C for up to 14 days. The manufacturer's package insert stated: "All iSTAT cartridges should be refrigerated at 2-8 C. Once removed from the refrigerator, cartridges may be stored at room temperature (18-30 C) for up to fourteen days. Once a cartridge has been warmed to room temperature, do not return it to the refrigerator. The manufacturer's labeled expiration date should be crossed out and the temperature expiration date should be written on the cartridge package." 4. The inspector inquired of the laboratory clinical coordinator regarding the laboratory's protocols for the iSTAT reagent cartridges stored at room temperature. The clinical coordinator stated, at approximately 3:05 PM: "We store the cartridges in the refrigerator and pull out a few to keep at room temperature. We are to write a new expiration date on the packages once they are pulled out of the refrigerator. We do not test ACT very often, and did not notice it was not labeled." 5. In an exit interview with the laboratory clinical coordinator, on 02/23/21 at approximately 4:30 PM, the above findings were confirmed.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of the laboratory's College of American Pathologists (CAP) 2019 and 2020 proficiency testing (PT) records and interviews, the laboratory director (LD) failed to ensure: 1. documentation of evaluation of results and corrective action for five (5) of 5 unacceptable Urea Nitrogen results on the laboratory's CAP 2020 AQI-B chemistry module (*a repeat deficiency); 2. a review of the laboratory's hematology and chemistry PT performance in five (5) of sixteen (16) module events reviewed. See D5221, and D6018.

D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) results and an interview, the laboratory director (LD) failed to document review of the laboratory's hematology and chemistry PT performance in five (5) of sixteen (16) module events reviewed. Findings include: 1. Review of the laboratory's 2019 and 2020 College of American Pathologists (CAP) hematology and chemistry PT records (a total of 16 modules) revealed no documentation of review or evaluation of results by the LD for the following 5 modules: 2019 Activated Clotting Time Event A- no results retained; 2019 Activated Clotting Time Event B -off schedule PT samples reported with no scores; 2020 Activated Clotting Time Event A - no results retained. 2019 Prothrombin Time/INR Event C - off schedule PT samples reported with no scores. 2019 AQI iSTAT Chemistry Event B - off schedule PT samples reported with no scores. The inspector requested to review the results for the 2019 and 2020 Activated Clotting Time Event. The laboratory coordinator stated at approximately 4:00 PM: "I do not know why the results are not in with the other forms. I can print them from CAP website." The inspector requested to review documentation of review/evaluation of results for the 5 PT events outlined above. No records were available. 2. In an exit interview with the laboratory clinical coordinator, on 02/23/21 at approximately 4:30 PM, the above findings were confirmed.