Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1053182	10/25/2018
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, PLLC on October 25, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the laboratory's 2017 and 2018 College of American Pathologists (CAP) proficiency testing (PT) records and interview with the practice manager on October 25, 2018, it was determined that the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for hemoglobin in four (4) out of 4

	iSTAT AQI testing events reviewed resulting in unsuccessful PT performance. (Cross Reference D 2130.)
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of pre-survey checks, proficiency testing (PT) records, and interviews, the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for hemoglobin in four (4) of 4 iSTAT AQI testing events reviewed resulting in unsuccessful PT performance. **REPEAT DEFICIENCY Findings include: 1. In a pre-survey preparation review of the Centers for Medicare and Medicaid Services (CMS) Casper 0096 D report, the inspector noted the laboratory failed to attain a score of at least eighty (80) percent for hemoglobin in seven (7) of 7 testing events from 2016 to 2018. A pre-survey review of an off-site CLIA PT Desk Review performed on May 3, 2017, revealed that the laboratory was cited for failing to attain a score of at least 80 % of acceptable responses for hemoglobin for the following College of American Pathologists (CAP) events: 2016 3rd Event - score of 0% 2017 1st Event - score of 0% 2. Review of the laboratory's CAP PT record book on the day of the inspection, 10/25/18, revealed hemoglobin scores of less than 80% were reviewed by the lab director for the following Hematology events: 2017 2nd event - score of 0%, 2017 3rd event - score of 0%, 2018 1st event - score of 0%, 2018 2nd event - score of 0%. 3. The inspector asked the practice manager at approximately 1:00 PM to describe the plan of correction that was in place after the May 3, 2017 off site PT CLIA cited deficiencies for unsuccessful performance scores. The practice manager stated: "We do not perform or report hemoglobin on our Abbott iSTAT instrument when we report the chemistry panels. We have it turned off. We thought that we had taken care of this matter with CAP in 2017 but we continue to get the zero scores." The inspector asked for documentation that the laboratory had notified CAP that they did not test for hemoglobin on the iSTAT panel. No documentation was available. 4. The inspector called CAP's quality assurance (QA) technical support department, at approximately 1:15 PM, to inquire if there was documentation that the laboratory had requested to delete the hemoglobin testing from the AQI iSTAT proficiency module. During the telephone interview, the QA technologist found records that the laboratory had contacted them on 10/17/18 to request that hemoglobin be removed from testing. No previous requests were documented. 5. In an interview with the practice manager at approximately 2:00 PM, it was confirmed that the laboratory received the unsuccessful PT performance scores outlined above for non-submission of results.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: Based on review of policies, quality control (QC) documentation, and an interview, the laboratory failed to follow the established policy for Abbott iSTAT calibration verification in calendar year 2017 and up to the inspection on October 25, 2018. Findings include: 1. Review of the laboratory's Fresenius Vascular Care Policy and Procedures Manual revealed a QC policy (ID #45) and an attached QC guide chart labeled "Moderate Complexity Quality Checks for iSTAT" that stated: "perform calibration linearity check every six months". 2. Review of the iSTAT QC documentation for ProTime/INR and Activated Clotting Time (ACT) from October 2016 to 10/25/18 revealed one (1) calibration verification performed in May 2016. The inspector requested to review calibration verification studies for 2017 and 2018. No documentation was available for review. 3. In an interview with the practice manager at approximately 2:00 PM, it was confirmed that the laboratory failed to follow the established QC policy for linearity testing for twenty-four (24) of 24 months reviewed.