

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D1053182	(X3) Date Survey Completed 04/06/2020
Name of Provider or Supplier Vascular Access Services (Va Beach Endovascular)	Street Address, City, State 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 unannounced, off-site CLIA proficiency testing (PT) desk review was conducted for Vascular Access Services, PLLC on April 3rd and April 6, 2020 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	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Based on an off-site desk review of the laboratory's College of American Pathologists proficiency testing (PT) records (2019 Third Event, 2020 First Event) and interviews, the laboratory failed to attain a score of at least eighty percent of acceptable responses</p>

for Prothrombin Time and International Normalized Ratio in two consecutive Hematology testing events resulting in unsuccessful PT performance. See 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 a review of proficiency testing (PT) records and interviews, the laboratory failed to attain a score of at least eighty percent (80%) of acceptable responses for Prothrombin Time with International Normalized Ratio (INR) on two (2) consecutive Hematology testing events reviewed, resulting in unsuccessful PT performance. Findings include: 1. An unannounced off-site desk review of the laboratory's College of American Pathologists (CAP) Hematology Whole Blood WP3 module PT records (2019 Event 3, 2020 Event 1) revealed scores of less than 80% for the following 2 consecutive events: 2019 Event 3: Prothrombin Time with INR score 0% (failure to participate); 2020 Event 1: Prothrombin Time with INR score 60% (specimen WP3-02 and WP3-05 scored as unacceptable); resulting in an unsuccessful PT performance. 2. In an email correspondence with the clinical coordinator on 04/03/20 at approximately 3:00 PM, and a telephone interview and email with CAP technical support specialist on 04/06/20 at approximately 9:00 AM, the above findings were confirmed.