

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2109943	(X3) Date Survey Completed 08/18/2020
Name of Provider or Supplier Vascular Strategies Llc	Street Address, City, State 5110 Campus Drive, Suite 137, Plymouth Meeting, PA	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedure manuals and interview with the General supervisor (GS), the laboratory failed to establish a competency assessment procedure to assess 1 of 1 clinical consultant (CC), 1 of 1 Technical Supervisor (TS) and 1 of 1 GS for their regulatory responsibilities from 2018 to 2020. Findings Include: 1. On the day of survey, 08/18/2020, the laboratory could not provide a competency assessment procedure that assess the competency for regulatory personnel (1 of 1 CC, 1 of 1 TS and 1 of 1 GS) from 4/6/2018 to 8/18/2020. 2. The GS could not provide competency assessment documentation for 1 of 1 CC, 1 of 1 TS and 1 of 1 GS for 2018, 2019 and 2020. 3. The GS confirmed the finding above on 08/18/2020 around 09:25 am.</p>
D6121	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.</p> <p>This STANDARD is not met as evidenced by: Based on review of competency assessment records and interview with the general supervisor (GS), the technical supervisor (TS) failed to include direct observation of</p>

performance for processing and testing for 2 of 2 testing personnel (TP) who performed molecular FRAT Binding and blocking testing in 2018, 2019 and 2020. Findings Include: 1. On the day of survey, 08/18/2020, review of 2 of 2 TP competency assessment records revealed, direct observation of performance for processing and testing of FRAT binding and blocking testing were not assessed in their competency assessment from 2018, 2019 and 2020. 2. The GS confirmed the finding above on 08/18/2020 around 10:15 am.

D6168

TESTING PERSONNEL
CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:
Based on review of the CLIA's Laboratory Personnel Report (Form CMS-209), review of personnel qualification records, and interview with general supervisor (GS), the laboratory failed to ensure that each individual performing High Complexity testing (1 of 2) is qualified. Refer to D6171

D6171

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high

school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on review of the CLIA's Laboratory Personnel Report (Form CMS-209), review of personnel qualification records, and interview with general supervisor (GS), the laboratory failed to ensure that each individual performing High Complexity testing (1 of 2) is qualified. Finding Include: 1. On the day of survey, 08/18/2020 review of testing personnel (TP) #2's Montgomery County Community College transcript revealed, TP#2 did not graduate from the college and took 12 credits in Biology and 8 credits in Chemistry (20/24 credits). 2. The GS was given until a week (until 08/25/2020) to provide acceptable educational credentials for TP#2. 3. On 08/26 /2020 around 03:20 pm, the GS could not provide the minimal acceptable educational credentials for TP#2 to perform high complexity testing.