

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2109943	(X3) Date Survey Completed 08/27/2024
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
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on document review and interview with the Technical Supervisor (TS), the Laboratory director (LD) failed to be present for a reasonable period of each working day in each laboratory for which he was director from 10/11/22 to the day of survey as required by Pennsylvania (PA) state regulations. Findings include: 1.The PA State regulation 5.22 (g) states: "A director shall be present for a reasonable period of each working day in each laboratory for which he is director." 2. Review of Application for Approval to Direct more than Two Clinical Laboratories (Exception to 5.22) form, revealed LD currently oversees 5 compliance/accredited laboratories, with 3 of the 5 laboratories located out of the state of PA. 3. During an interview on 08/27/2024 at 10:45 am, the TS (CMS 209 personnel #2) stated that: "the LD is only on site quarterly, sometimes more." 4. The TS confirmed the findings above on 08/27/2024 at 10:45 am</p>
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 competency assessment records, lack of documentation, and</p>

interview with the technical supervisor (TS), the laboratory failed to establish a competency assessment procedure to assess 1 of 2 general supervisors (GS) for their supervisory responsibilities from 10/11/2022 to the day of survey. Findings Include:

1. On the day of survey, 08/27/2024 at 09:00 am, the laboratory failed to provide a competency assessment procedure to assess the competency of 1 of 2 GS (CMS 209 personnel #4) for their supervisory responsibilities from 10/11/2022 to 08/27/2024.
2. The laboratory failed to provide competency assessment documentation for 1 of 2 GS (CMS personal #4) from 10/11/2022 to 08/27/2024.
3. The TS confirmed the findings above on 08/27/2024 at 10:45 am.