

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D2190168	<b>(X3) Date Survey Completed</b>  09/05/2024
<b>Name of Provider or Supplier</b>  Penn Fertility Care Lancaster General Health	<b>Street Address, City, State</b>  2112 Harrisburg Pike, Suite 110, Lancaster, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3009</b>	<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 Laboratory director (LD), the LD failed to be present for a reasonable period of each working day in each laboratory for which they were director from 08/12/2020 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.On day of survey 09/05/2024, review of the PA Application for Approval to Direct more than Two Clinical Laboratories (Exception to 5.22) form, revealed the LD currently oversees 4 accredited laboratories, with 3 of the 4 laboratories located out of the state of PA. 3. Penn Fertility Care personnel policy states " The Laboratory Director will provide approximately thirty (30) hours of service per month. It is anticipated that visits will take place a minimum of four (4) times per year." 4. Further review of the laboratory's Quality Assessment Site Visit Logs revealed the LD was on site once a quarter. 5. The LD confirmed the findings above on 09/05/2024 at 11:45 am</p>
<b>D5209</b>	<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>

This STANDARD is not met as evidenced by:

Based on review of competency assessment records and interview with the Laboratory Director (LD), the laboratory failed to establish a competency assessment procedure to assess 1 of 2 Technical Supervisors (TS) and 1 of 1 General supervisor (GS) for their supervisory responsibilities from 11/10/2020 to the day of survey. Findings Include: 1. On the day of survey, 09/05/2024 at 9:25 am, the laboratory failed to provide a competency assessment procedure to assess the competency of 1 of 2 TS (CMS 209 personnel #4) and 1 of 1 GS (CMS 209 personnel #5) for their supervisory responsibilities from 11/10/2020 to 09/05/2024. 2. The laboratory failed to provide competency assessment documentation for 1 of 1 GS (CMS 209 personnel #5) from 11/10/2020 to 09/05/2024. 3. The LD confirmed the findings above on 09/05/2024 at 11:40 am