

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D2128154	<b>(X3) Date Survey Completed</b>  07/17/2025
<b>Name of Provider or Supplier</b>  Patient First - Downingtown	<b>Street Address, City, State</b>  967 E Lancaster Avenue, Downingtown, 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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 (CA), quality assurance and quality control records (QA/QC), lack of documentation, and interview with the Technical Consultant (TC) #1, the laboratory failed to assess the competency of 1 of 1 testing personnel (TP) that performed the position responsibilities of a TC from 7/5/2023 to 7/17/2025. Findings Include: 1. On the day of survey, 7/17/2025 at 10:30 am, review of CA and QA/QC records revealed 1 of 1 TP (CMS 209, TP#1) performed the following duties of a CLIA TC based on 493.1413(b)(8) Standard, Technical Consultant Responsibilities: - Direct observations for CA for TP #2 and TP #3 (Form CMS 209, dated 7/11/2025) in 2024. - QA/QC reviews for the following 6 of 24 months from 7/5/2023 to 7/17/2025: August 2023 December 2023 March 2024 September 2024 January 2025 June 2025 2. The laboratory failed to provide a competency assessment for TP #1 (CMS 209 form dated 7/11/2025) for their TC responsibilities performed in the laboratory from 7/5/2023 to 7/17/2025. 3. The laboratory failed to provide written documentation for which responsibilities the Laboratory Director delegated to TP #1 from 7/5/2023 to 7/17/2025. 4. Technical Consultant (TC) #1 confirmed the findings above on 7/17/2025 at 11:30 am.</p>