

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0880382	(X3) Date Survey Completed 06/20/2025
Name of Provider or Supplier Comprehensive Pediatrics Pc	Street Address, City, State 1407 West 6th Street, Brooklyn, NY	
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
D5785	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)</p> <p>(b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of Quality Control (QC) material storage requirements, Standard Operating Procedures (SOPs), as well as interview with the Testing Personnel (TP), the laboratory failed to comply with QC material storage requirements and document corrective action for out-of-range temperatures.</p> <p>FINDINGS: 1. The QC material manufacturer's requirements specified storage temperature of 2 - 8C (36 - 46F). 2. Out of range temperatures were documented for six days in April 2024 and six days in May 2024 for the refrigerator where QC materials were stored. 3. There was no documentation of corrective action performance. 4. This was contrary to instructions indicated in the current, approved SOPs. 5. It was noted that QC control performed during the respective period was acceptable. 6. The TP confirmed the findings on June 20, 2025, at 12:00 P.M.</p>