

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 08D0984700	(X3) Date Survey Completed 07/31/2025
Name of Provider or Supplier Gastroenterology Clinical Laboratory	Street Address, City, State Nemours Children'S Hospital, Delaware, Wilmington, DE	
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
D0000	A Recertification Survey was conducted on July 31, 2025 at approximately 9:00AM. The laboratory was surveyed according to 42 CFR Part 493 Clinical Laboratory Improvement Amendments (CLIA) requirements. Deficiencies were identified as follows:
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(b)(7) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on interview and laboratory document and policy review, the laboratory failed to have signed proficiency testing (PT) attestation forms for 9 out of 9 PT events reviewed. Findings included: A laboratory policy titled, "2.4.2 Proficiency Test Policy (External Assessment Test)," including a "Procedure Review / Signature" page signed by Laboratory Director (LD) #1 on 07/10/2024, revealed, "10. PT Records 10.1 GI [gastrointestinal] Lab maintains records of each PT event, including a copy of the PT program report forms, work records, evaluation reports, and any corrective action /summary reports if applicable." There were no instructions for personnel to sign the attestation forms when submitting PT results. The laboratory's PT documentation for the following PT events revealed there were no signed attestation forms to indicate the PT samples were handled as required by Clinical Laboratory Improvement Amendments (CLIA) regulations: - FCAL-A 2023 Fecal Calprotectin - CES-B 2023 Celiac Serology - FCAL-B 2023 Fecal Calprotectin - FCAL-A 2024 Fecal Calprotectin - FCAL-B 2024 Fecal Calprotectin - CES-A 2024 Celiac Serology - CES-B 2024 Celiac Serology - FCAL-A 2025 Fecal Calprotectin - CES-A 2025 Celiac Serology During an interview on 07/31/2025 at 1:15 PM, Technical Supervisor /General Supervisor (TS/GS) #2 was asked for the signed attestation forms for the</p>

nine PT events reviewed. TS/GS #2 stated the personnel responsible for the PT process had retired. TS/GS #2 was unable to provide documentation of the signed attestation forms for the nine PT events reviewed.