

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0997501	(X3) Date Survey Completed 05/17/2022
Name of Provider or Supplier Ppd, Part Of Thermofisher Scientific	Street Address, City, State 2244 Dabney Road , Building C, Richmond, VA	
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	An announced CLIA recertification survey was conducted at PPD Development, LP on May 16-17, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited is as follows:
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, lack of documentation, and an interview, the laboratory failed to retain their PT attestation statements signed by the testing personnel for three (3) of five (5) Erythropoietin challenged events in the twenty-six (26) months reviewed (March 2020 to May 17, 2022). Findings include: 1. Review of the laboratory's 2020, 2021, and year to date 2022 College of American Pathologists (CAP) Erythropoietin PT documentation, a total of 5 events (2020 Events A-B, 2021 Events A-B, 2022 Event A), revealed no CAP signed attestation statement by the testing personnel for: CAP Ligand-Special Erythropoietin Y-A 2020, CAP Ligand-Special Erythropoietin Y-B 2020, CAP Ligand-Special Erythropoietin Y-B 2021. 2. Review of the PT records outlined above revealed CAP attestation instructions: "The laboratory director or designee and the testing personnel must sign on the result form. Retain a signed copy of this page in your laboratory for your records and inspection purposes." The inspector requested to review the signed attestation documentation for the 3 events listed above. No documentation was available for review. 3. An interview with the laboratory manager on 5/17/22 at approximately 4:30 PM confirmed the findings.</p>