

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2164581	(X3) Date Survey Completed 03/18/2021
Name of Provider or Supplier Thplasma Fair Lawn	Street Address, City, State 23-04 Broadway, Fair Lawn, NJ	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) 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 surveyor review of the Proficiency Testing (PT) records and interview with the Office Manager (OM), the laboratory failed to maintain Work Records (WR) for Chemistry test performed with the American Association of Bioanalysts (AAB) on events A, B, and C in 2020 events. The OM confirmed on 3/18/21 at 11:15 am that the laboratory did not maintain WR records for PT. .</p>