

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2164581	(X3) Date Survey Completed 04/22/2025
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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Performance Specification (PS) records and interview with the Laboratory Director of Quality (DQ), the laboratory failed to ensure that all PS records were adequate for total protein test run on the Reichert Technologies TS Meter from May 2023 to 4/22/25. The findings include: 1. There was no Normal Patient Range study performed. 2. The DQ confirmed on 4/22/25 at 11:30 am, the laboratory failed to ensure that all PS records were adequate.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p>

This STANDARD is not met as evidenced by:
Based on surveyor review of the Test Reports (TR) for Total Protein and interview with the Director of Quality (DQ) the laboratory failed to ensure the TR included all the required information from May 2023 to 4/22/25. The findings include: 1. TR did not include the name address of the laboratory where Routine chemistry was performed. 2. The DQ confirmed on 4/22/25 at 12:00 pm, the laboratory failed to ensure the TR included all the required information.

D5807

TEST REPORT
CFR(s): 493.1291(d)

(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Final Report (FR), Procedure Manual (PM), and interview with the Director of Quality (DQ), the laboratory failed to ensure that the Reference Interval (RI) was accurate for total protein run on the Reichert Technologies TS meter from May 2023 to 4/22/25. The finding includes: 1. There was no RI on the FR for Total Protein. 2. The DQ confirmed on 4/22/25 at 11:30 am that the laboratory failed to ensure the RI was accurate.