

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2164581	(X3) Date Survey Completed 05/02/2023
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
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Quality Assurance Manager (QAM) the laboratory failed to review and evaluate results when they received an unacceptable score for total protein tests performed with the American Association of Bioanalysts (AAB), for event Q3-2022. The findings include: 1. The laboratory received an "*", "out of grading range or incorrect response" for sample 11 Total Protein in AAB event Chemistry Q3-2022. 2. There was no documented evidence that the laboratory reviewed the failed test result. 3. The QAM confirmed on 5/2/23 at 10:45 am that the laboratory did not review and document an evaluation of unacceptable PT results.</p>
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p>

This STANDARD is not met as evidenced by:
Based on surveyor review of the Procedure Manual (PM), Competency Assessment (CA) and interview with the Quality Assurance Manager (QAM) the Laboratory Director (LD) failed to establish a CA procedure with the required elements for Total Protein testing from 3/18/21 to the date of the survey. The findings include: 1. There was no documented evidence that intermediate test results, worksheets, quality control records, proficiency testing results, and preventive maintenance records were reviewed for the CA. 2. There was no documented evidence that assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples were reviewed for the CA. 3. The QAM confirmed on 5/2/23 at 1:40 pm that a CA was not maintained.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Personnel Files, Competency Assessment records and interview with the Quality Assurance Manager (QAM), the Technical Consultant (TC) failed to perform CA from 3/18/21 to the date of survey. The findings include: 1. The CA was not performed by the TC but was done by a non qualified testing personnel 2. The QMA confirmed on 5/2/23 at 10:15 am that the CA was not performed by the TC.