

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D2221005	<b>(X3) Date Survey Completed</b> 03/07/2023
<b>Name of Provider or Supplier</b> Thplasma Elizabeth	<b>Street Address, City, State</b> 81 Broad Street, Elizabeth, NJ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5775</b>	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Laboratory Records and interview with the Corporate Quality Manager (CQM), the laboratory failed to perform and document correlation studies for Total Protein performed on the REICHERT Digital Refractometer analyzers twice per year from June 2021 to the date of the survey. The CQM confirmed on 3/7/23 at 11:20 am that the laboratory did not do correlation studies.</p>
<b>D5803</b>	<p>TEST REPORT CFR(s): 493.1291(b)</p> <p>Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor review of Donor Records (DR) the lack of Final Reports (FR) and interview with the Corporate Quality Manager (CQM), the laboratory failed to have FR on one five of five DR reviewed on the date of survey. The CQM confirmed on 3/7/23 at 11:00 am that the laboratory did not maintain all FR.</p>
<b>D6013</b>	LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(ii)

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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:

Based on surveyor review of the Performance Specification (PS) records and interview with the Corporate Quality Manager (CQM), the Laboratory Director (LD) failed to ensure that PS procedures performed for Total Protein tests performed on the Reichert digital refractometer were adequate from June 2021 to the date of survey. The findings include: 1. There was no evidence that a Reference Range was verified on nine out of nine analyzers. 2. The CQM confirmed on 3/7/23 at 11:15 am that PS records were not adequate.

**D6074**

**TESTING PERSONNEL RESPONSIBILITIES**

CFR(s): 493.1425(b)(5)

Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Quality Control (QC) records and interview with the Corporate Quality Manager (CQM), the Testing Personnel failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts of Routine Chemistry QC results performed on the REICHERT Digital Refractometer analyzers from June 2021 to the date of the survey. The CQM confirmed on 3/7/23 at 11:10 am that trends and shifts were not reviewed.