

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2172786	<b>(X3) Date Survey Completed</b>  06/30/2021
<b>Name of Provider or Supplier</b>  Csl Plasma, Inc - El Paso 279	<b>Street Address, City, State</b>  6351 S. Desert Blvd, Suite 212b, El Paso, TX	
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>D5421</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 review of the laboratory's verification studies performed on its 7 Reichert refractometers in October 2019, Reichert Technologies Quick reference guide and staff interview, it was revealed the laboratory failed to have documentation of verifying the reportable range for total protein. The findings included: 1. A review of the laboratory's verification studies performed on the Reichert refractometers in October 2019 revealed the facility failed to have documentation of verifying the reportable range for total protein. 2. The laboratory was asked to provide documentation of verification of the reportable range study but none was provided. 3. Review of the Reichert Technologies quick reference guide found on page 2 under the heading Results- " The meter's range is 0.0 to 15.1 g/100 mL plasma protein." 4. Interview with the technical consultant conducted June 30 2021 at 1216 PM in the conference room confirmed the findings.</p>