

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  37D2151373	<b>(X3) Date Survey Completed</b>  01/19/2021
<b>Name of Provider or Supplier</b>  Csl Plasma, Inc	<b>Street Address, City, State</b>  140 South Symes Ln, Mustang, OK	
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>D0000</b>	The recertification survey was performed on 01/19/2021. The findings were reviewed with the technical consultant/assistant center manager, quality specialist, and the director of operations and quality during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with the technical consultant/assistant center manager and the quality specialist, the laboratory failed to ensure materials were not used beyond the open vial stability. Findings include: (1) On 01/19/2021 at 9:30 am the technical consultant/assistant center manager stated the following to the surveyor: (a) Plasma Total Protein was tested at five stations using the Reichert TS Meter DSP analyzers; (b) KOVA Refractrol SP control materials were used for calibration and daily quality control (using different lot numbers). (2) Surveyor #2 reviewed the manufacturer's package insert for the control materials. The insert stated, "Refractrol SP has an open vial stability of up to 14 days"; (3) On 01/19/2021 at 09:50 am, surveyor #2 observed the Normal level (lot #K303960), being used as a calibrator and identified the following: (a) The bottle had been dated as opened on 12/22/20 and was available for use. (4) On 01/19/2021 at 10:00 am, the technical consultant/assistant center manager stated to surveyor #2 the material was available for use as indicated above.</p>