

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D0670222	<b>(X3) Date Survey Completed</b> 05/04/2022
<b>Name of Provider or Supplier</b> Csl Plasma Inc	<b>Street Address, City, State</b> 1001 Corridor Park Blvd, Knoxville, TN	
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>	Intakes: TN00057000 ===== The CSL Plasma, Inc was found to be in compliance with the requirements at 42 CFR, part 493, "Requirements for Laboratories" as a result of an on-site complaint investigation 05/03 /2022 and 05/04/2022. =====
<b>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: ===== Based on patient chart reviews, review of the chemistry analyzer's maintenance records and interview with the Laboratory Operations Manager, determined that daily maintenance was not performed on the chemistry analyzer on 2.8.2022. The findings include: 1. A review of patient chart reviews revealed 8250 patient samples were analyzed on the chemistry analyzer on 2.8.2022 2. A review of the chemistry analyzer's maintenance records for February 2022 revealed daily maintenance was not completed on 2.8.2022. 3. An interview with the Laboratory Operations Manager at approximately 11:00 a.m. on May 4, 2022 confirmed the daily maintenance was not performed on the chemistry analyzer on 2.8.2022. =====</p>
<b>D5791</b>	<p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The</p>

laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

===== Based on review of the "Lab QA Roles and Responsibilities" policy, review of February 2022 maintenance records for two chemistry analyzers, and upon interview with Lab Operations Manager, determined the laboratory failed to follow policy regarding quality assessment (QA) review within 15-30 days. The findings include: 1. A review of the Lab QA Roles and Responsibilities policy states, "QA review of routine maintenance logs is performed on a monthly basis within 15 days after the logs are submitted to QA or 30 days for exceptions." 2. A review of February 2022 maintenance records for two chemistry analyzers revealed QA reviewed February 2022 maintenance records for two chemistry analyzers on 05.03.2022. 3. An interview with the Lab Operations Manager at approximately 11:00 a.m. on May 4,2022 determined the laboratory failed to follow policy regarding QA review within 15-30 days.

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