

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2064762	(X3) Date Survey Completed 12/13/2018
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 1283 Columbia Drive, Decatur, GA	
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
D0000	A proficiency testing desk review was completed on December 13, 2018. At the time of the review, the laboratory was not in compliance with the Clinical Laboratory Improvement Amendments of 1988, 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in three of five consecutive events (1 and 3rd events of 2017 and 2nd</p>

event of 2018), resulting in the second unsuccessful occurrence for Routine Chemistry analyte # 245 including: Total Protein, analyte # 485. Findings include: Refer to D 2096 & D 2089

D2089

ROUTINE CHEMISTRY
CFR(s): 493.841(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's proficiency testing (PT) reports and an on-line chat with a representative from the laboratory's proficiency testing agency, the American Association of Bioanalysts (AAB), the laboratory failed to submit results for the 2nd event of 2018. This resulted in receiving scores of 0%, which resulted in the second unsuccessful occurrence for Routine Chemistry analyte # 245 including: Total Protein, analyte # 485. Findings include: 1. Desk review of the laboratory's proficiency testing reports from the American Association of Bioanalysts (AAB) revealed the laboratory received scores of 0% for Routine Chemistry and Total Protein on event 2 of 2018. 2. An On-line chat with a representative from AAB on November 7, 2018 at am 11:30 am confirmed the laboratory did not submit results for the 2nd event of 2018 so they received scores of 0%. This resulted in the second unsuccessful performance for Routine Chemistry, analyte #245 and Total Protein, analyte # 485.

D2096

ROUTINE CHEMISTRY
CFR(s): 493.841(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in three of five consecutive events (1st and 3rd events of 2017 and 2nd event of 2018), resulting in the second unsuccessful occurrence for Routine Chemistry analyte # 245 including: Total Protein, analyte # 485. Findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed the speciality of Routine Chemistry, analyte # 245 and analyte #485 Total Protein on event 1 of 2017 with a score of 60%, event 3 of 2017 with a score of 40% and event 2 of 2018 with a score of 0% for non-participation. 2. Desk review of the laboratory's proficiency testing reports from the American Association of Bioanalysts (AAB)confirmed the

	<p>laboratory failed Routine Chemistry and Total Protein on Events 1 and 3 of 2017 and Event 2 of 2018 resulting in the second unsuccessful performance.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports, the laboratory director failed to ensure the laboratory maintained satisfactory performance in three of five consecutive events (1st and 3rd events of 2017 and 2nd event of 2018), resulting in the second unsuccessful occurrence for Routine Chemistry analyte # 245 including: Total Protein, analyte # 485. Findings include: Refer to D6016</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports, the laboratory director failed to ensure the laboratory maintained satisfactory performance in three of five consecutive events (1st and 3rd events of 2017 and 2nd event of 2018), resulting in the second unsuccessful occurrence for Routine Chemistry analyte # 245 including: Total Protein, analyte # 485. Findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed the speciality of Routine Chemistry, analyte # 245 and analyte #485 Total Protein on event 1 of 2017 with a score of 60%, event 3 of 2017 with a score of 40% and event 2 of 2018 with a score of 0% for non-participation. 2. Desk review of the laboratory's proficiency testing reports from the American Association of Bioanalysts (AAB) confirmed the laboratory failed Routine Chemistry and Total Protein on Events 1 and 3 of 2017 and Event 2 of 2018 resulting in the second unsuccessful performance.</p>