

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2036555	(X3) Date Survey Completed 05/01/2018
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 820 Madison Square, Madison, TN	
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
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: ALWAYS REFER TO STANDARD TAG IN APPROPRIATE LAB SPECIALTY. Hematology: The laboratory failed to maintain satisfactory participation in two out of three events for the Hematocrit Analyte, resulting in the first unsuccessful proficiency testing (PT) occurrence for Hematocrit analyte. (Refer to D2130)</p>
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive</p>

events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on review of the Casper report 155D, the American Association of Bioanalysts (AAB) report from the laboratory's 2016 and 2017 Proficiency Testing (PT) records, and interview with the laboratory supervisor, the laboratory failed to maintain satisfactory performance for the Hematocrit analyte in 2016 Event three and 2017 Event one, resulting in the first unsuccessful occurrence. The findings include: 1) Review of the Casper report 155D revealed the laboratory failed to maintain satisfactory performance for the Hematocrit analyte in 2016 Event three and 2017 Event one, resulting in the first unsuccessful occurrence. 2) Review of the AAB report from the laboratory's 2016 event three PT reports revealed sample numbers 1-5 had no grades for Microhematocrit, resulting in a score of 0% and in 2017 event one PT reports revealed sample numbers 1-4 had unacceptable grades for Microhematocrit resulting a score of 40%. 3) In an interview, on May 1, 2018 at 12:30 PM, the laboratory supervisor confirmed the unsatisfactory results for the third event in 2016 and first events of 2017 resulting in the First Unsuccessful Performances in Hematocrit analyte test.