

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2123107	(X3) Date Survey Completed 05/16/2019
Name of Provider or Supplier Csl Plasma Inc	Street Address, City, State 1655 S College St Suite C, Auburn, AL	
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
D6054	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the personnel records, interviews with the Manager of Quality and the Center Manager, and a review of the policy and procedure, the surveyor determined the laboratory Technical Consultant failed to assess the competency of the laboratory testing personnel (of moderate complexity) at least annually after the initial training. This affected four of twelve testing personnel, who performed moderate complexity testing. The findings include: 1. A review of the personnel records revealed at least four of twelve testing personnel's competency was not assessed annually after the initial laboratory training. See the following: a) Testing Personnel (TP) #1's date of hire was noted as July 16, 2017. TP #1 was initially trained on the laboratory tasks, including testing, in April of 2018 (4/19/2018). The "periodic" competency assessment was done on 11/13/2018 and was explained as a semiannual competency assessment. No annual assessment had been done. In an interview at 9:46 AM, the Manager of Quality (the Center Manger was present), stated the annual assessment will be done in November of 2019. The Manager of Quality explained the annual assessment dates are scheduled in the electronic system to occur approximately one year from the first "periodic" assessment completed (for TP #1, on 11/13/18). The laboratory's descriptive terminology for all assessments is "periodic." b) TP # 4's date of hire was noted as 7/24/2017, and initial training was completed on 8/29/2017. The first periodic competency assessment was done on 6/21/2018. There were no other competency assessments documented for TP #4. At 10:50 AM, the Manager of Quality stated the personnel's competency had not been assessed, since June of 2018, but will be assessed next month (June of 2019), nearly two years from the date of</p>

initial training. c) TP #6 was hired on 4/14/2018 and completed initial training on 4/19/2018. The first periodic competency assessment was completed on 10/09/2018. There was no additional documentation of competency assessments. At 10:52 AM, the Quality Manager confirmed the above noted findings. d) TP #7's start date was noted as 3/18/2018, and initial training was completed on 3/29/2018. The periodic competency assessment occurred on 9/18/2018. No other competency assessments were documented for TP #7. 2. A review of the policy and procedure revealed the following: "Employees will complete an annual training requirement to ensure continued competency in learning objectives. The documentation of the completion certification curriculum will apply a requirement to reassess knowledge and performance through an annual curriculum at an interval of 365 days unless otherwise stated in the Ignite program guide..."