

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2055945	(X3) Date Survey Completed 08/08/2018
Name of Provider or Supplier Csl Plasma Inc	Street Address, City, State 14004 Nacogdoches Road, San Antonio, TX	
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	An entrance conference was held 08/08/2018 with the Assistant Manager of Quality and the Center Manager. The survey process was discussed. An opportunity for questions and comments was given. Based upon the onsite survey conducted, this facility was found NOT to be compliance with CLIA regulations found at 42 CFR for the specialties/subspecialties in which it was surveyed. Condition 493.1421 Laboratory Testing Personnel An exit conference was held on 08/08/2018 with the Technical Consultant, the Assistant Manager of Quality and the Center Manager. The exit conference attendee was advised the laboratory was out of compliance and advised of conditions and deficiencies found during the survey. An opportunity for questions and comments was provided.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS-209, review of the laboratory's personnel records and staff interview, it was revealed that the laboratory failed to have documentation of competency assessment for the technical consultant. Findings included: 1. Review of the laboratory's submitted Form CMS-209 (signed by the laboratory director on 08/08/2018) revealed the laboratory identified 1 Technical Consultant. 2. A review of the laboratory's personnel record titled "Annual Recertification--Lab Director or Technical Consultant" revealed a competency assessment was performed on 08/11/2017 with initials "AC" as the person performing the assessment. This person did not meet the requirements of laboratory director; therefore, was not qualified to perform the technical consultant's competency assessment. 3. During an interview with the technical consultant on 08/08/2018 at</p>

	<p>1038 am in the conference room, the laboratory was asked to provide documentation that the lab director performed the technical consultant's competency assessment. No documentation was provided. This confirmed the findings.</p>
<p>D6049</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, it was revealed the technical consultant failed to include the review of quality control (QC) results as part of the competency assessment for 30 of 30 testing personnel. Findings included: 1. A review of the laboratory's personnel records revealed the technical consultant failed to ensure that the review of quality control results was part of the competency assessment for 30 of 30 testing personnel. The laboratory was asked to provide documentation that QC review was part of competency assessment. No documentation was provided. 2. An interview with the technical consultant on 08/08 /2018 at 1126 am in the conference room revealed this element was NOT part of the laboratory's competency assessment for testing personnel.. This confirmed the findings.</p>
<p>D6063</p>	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory's submitted Form CMS-209, review of the laboratory's personnel records and staff interview, it was revealed that the laboratory failed to have documentation of education to qualify 1 of 30 testing personnel to perform moderate complexity testing. (Refer to D6065)</p>
<p>D6065</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and</p>

This STANDARD is not met as evidenced by:

Based on review of the laboratory's submitted Form CMS-209, review of laboratory's personnel records and staff interview, it was revealed that the laboratory failed to have documentation of education to qualify 1 of 30 testing personnel to perform moderate complexity testing. Findings included: 1. A review of the laboratory's submitted Form CMS-209 revealed the laboratory identified 30 personnel who performed testing since the previous survey. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of education to qualify 1 of the testing personnel to perform moderate complexity testing. The personnel was (as listed on the Form CMS-209) a. Testing person 23 employed 05/01/2017 to present Malaysian Certificate of Education No equivalent foreign credentialing was provided. 3. The laboratory was asked to provide documentation to qualify the identified personnel. No documentation was provided. 4. An interview with the Assistant Manager of Quality on 08/08/2018 at 0950 am in the conference room revealed the reviewed records were the only education documents that the facility had for the identified personnel. This confirmed the findings.