

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2159592	(X3) Date Survey Completed 05/25/2023
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 8825 N Loop Dr Suite 116, El Paso, 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
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Review of proficiency testing records and interview of facility personnel found that the laboratory failed to obtain a score of at least 80 percent for the analyte Total Protein in one of five Chemistry testing events between 2021 Q3 and 2023 Q1 (three testing events per year). Findings included: 1. Review of the American Association of Bioanalysts (AAB) Chemistry proficiency testing records for 2021 Q3 through 2023 Q1 (3 testing events per year) found that the laboratory achieved a score of 60% for Total Protein in the Chemistry Q3 2022 testing event constituting unsatisfactory analyte performance. 2. During interview of the Assistant Manager of Quality conducted May 25, 2023 at 11:04 AM, she confirmed that the laboratory failed to achieve an acceptable score of at least 80% for Total Protein in the Chemistry Q3 2022 testing event.</p>
D2088	<p>ROUTINE CHEMISTRY CFR(s): 493.841(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Review of proficiency testing records and interview of facility personnel found that the laboratory failed to attain an overall score of at least 80 percent in one of five Chemistry testing events between 2021 Q3 and 2023 Q1 (three testing events per</p>

year). Findings included: 1. Review of the American Association of Bioanalysts (AAB) Chemistry proficiency testing records for 2021 Q3 through 2023 Q1 (3 testing events per year) found that the laboratory achieved a score of 60% for Total Protein in the Chemistry Q3 2022 testing event constituting unsatisfactory performance. 2. During interview of the Assistant Manager of Quality conducted May 25, 2023 at 11:04 AM, she confirmed that the laboratory failed to achieve an overall event score of at least 80% in the Chemistry Q3 2022 testing event.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on a review of the Laboratory Personnel Report, policies and procedures, personnel records and staff interview, the laboratory director failed to ensure that one of thirty seven testing personnel had obtained the appropriate documented training required prior to testing specimens for Total Protein using the Reichert digital refractometer (see D6066).

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of the CMS 209 Laboratory Personnel Report, laboratory policies and procedures, personnel records and interview of facility personnel found that the Technical Consultant failed to evaluate and document the competency of testing personnel at least semiannually in the first year of testing for three of thirty seven testing personnel listed on the CMS Report 209. Findings included: 1. Review of the CMS Report 209 Laboratory Personnel Report found the laboratory listed thirty seven testing personnel performing moderate complexity testing. 2. Review of Document CPU-FORM-00166476 titled CLIA Personnel Reference Guide (Ver. 5.0) found on page 8 under the heading Specific training for Testing Personnel: " Only trained personnel with approval of the Technical Consultant may independently perform regulated testing. Competency is evaluated during initial training, at six months, at twelve months, and annually thereafter or whenever testing methodology changes." 3. Review of laboratory personnel records found no documentation of semi-annual competency assessments for three of thirty seven testing persons as follows: Testing person five (initial training completed 09/27/2022) Testing person twenty five (initial training completed 1/25/2022. Testing person twenty seven (hire date 07/25/2021, no

	<p>initial training available for review). 2. During Interview of the assistant manager of quality conducted May 25, 2023 at 10:00 AM, she confirmed that semi-annual competency assessment for the three testing personnel were available for review and that this was detected in their own internal audit.</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 a review of the Laboratory Personnel Report, policies and procedures, personnel records and staff interview, it was revealed that one of thirty seven testing personnel did not have the appropriate documented training required to perform moderate complexity testing (see D6066).</p>
<p>D6066</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii)</p> <p>Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of the CMS 209 Laboratory Personnel Report, laboratory policies and procedures, personnel records and interview of facility personnel found that one of thirty seven testing personnel listed on the CMS Report 209 had no documentation of training prior to testing patient specimens using the Reichert Digital refractometer for testing Total Protein. Findings included: 1. Review of the CMS Report 209 Laboratory Personnel Report found the laboratory listed thirty seven testing personnel performing moderate complexity testing. 2. Review of Document CPU-FORM-00166476 titled CLIA Personnel Reference Guide (Ver. 5.0) found on page 8 under the heading Specific training for Testing Personnel: " Only trained personnel with approval of the Technical Consultant may independently perform regulated testing. Competency is evaluated during initial training, at six months, at twelve months, and annually thereafter or whenever testing methodology changes." 3. Review of laboratory personnel records found no documentation of training for testing person twenty seven (hire date 07/25/2021)listed on the CMS Report 209. Training records were requested but not provided. 2. During Interview of the assistant manager of quality conducted May 25, 2023 at 10:25 AM, she confirmed that no training records were available for review for testing person twenty seven and that this was detected in their own internal review.</p>