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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>19D2105502 | <b>(X3) Date Survey Completed</b><br><br>02/05/2018 |
| <b>Name of Provider or Supplier</b><br><br>Csl Plasma, Inc   | <b>Street Address, City, State</b><br><br>2532 Williams Blvd, Kenner, LA   |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>   |
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| <b>D0000</b>              | A Certification survey was performed at CSL Plasma, INC-CLIA # 19D2105502 on February 5, 2018. CSL Plasma, INC was found not in compliance with the following <b>CONDITION LEVEL DEFICIENCY: 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing; Laboratory Director 42 CFR 493.1421 CONDITION: Laboratories performing moderate complexity testing; Testing Personnel</b>   |
| <b>D2007</b>              | <p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b><br/>CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by:<br/>Based on record review and interview with personnel, the laboratory failed to ensure that proficiency testing was performed by personnel who routinely perform laboratory testing. Findings: 1. Review of the laboratory's American Association of Bioanalysts proficiency testing records for 2017 and 2018 revealed the following personnel performed proficiency testing for evaluation: 2017 Chemistry 2nd Quarter-Personnel 16 2. In interview on February 5, 2018 at 10:30 am, Personnel 5 stated Personnel 16 was a visiting CSL Plasma tech from another state temporarily serving as a Quality Manager while she was on medical leave. Personnel 5 further stated Personnel 16 only performed the identified proficiency tests, not routine patient testing. 3. In further interview on February 5, 2018 at 10:42 am, Personnel 5 and Personnel 7 stated Personnel 16 did not have a state of Louisiana license for laboratory testing.</p> |
| <b>D6000</b>              | <p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b><br/>CFR(s): 493.1403</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.

This CONDITION is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure proficiency samples are tested as required. Refer to D6016. 2. The Laboratory Director failed to ensure testing personnel performing moderate complexity testing met state licensure requirements. Refer to D6029.

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(i)

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;

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure proficiency samples are tested as required. Refer to D2007.

**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 record review and interview with personnel, the Laboratory Director failed to ensure testing personnel performing moderate complexity testing met state licensure requirements. Refer to D6064.

**D6063**

**LABORATORY TESTING PERSONNEL**

CFR(s): 493.1421

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.

This CONDITION is not met as evidenced by:  
Based on record review and interview with personnel, the laboratory failed to provide documentation of individuals who meet the qualification requirements to perform the functions specified in a lab of moderate complexity. Refer to D6064.

**D6064**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1423(a)

Each individual performing moderate complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

This STANDARD is not met as evidenced by:  
Based on record review and interview with personnel, the laboratory failed to provide documentation of a current Louisiana state license through the Louisiana State Board of Medical Examiners (LSBME) for laboratory testing for one (1) of fourteen (14) testing personnel reviewed. Findings: 1. Review of the laboratory's American Association of Bioanalysts proficiency testing records for 2017 Chemistry 2nd Quarter revealed Personnel 16 performed proficiency testing for evaluation. 2. Review of personnel records for Personnel 16 revealed no documentation of a current Louisiana state license issued from LSBME for laboratory testing. 3. In interview on February 5, 2018 at 10:30 am, Personnel 5 stated Personnel 16 was a visiting CSL Plasma tech from another state temporarily serving as a Quality Manager while she was on medical leave. Personnel 5 further stated Personnel 16 only performed the identified proficiency tests, not routine patient testing. 4. In further interview on February 5, 2018 at 10:42 am, Personnel 5 and Personnel 7 stated Personnel 16 did not have a state of Louisiana license for laboratory testing.