

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2134446	(X3) Date Survey Completed 06/12/2019
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 3800 E State St, Rockford, IL	
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
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview; the laboratory director failed to ensure that prior to testing patient's specimens, all personnel had the appropriate education for performing moderate complexity testing. Findings include: 1. Review of Laboratory Personnel Report (FORM -CMS 209) revealed that the laboratory listed a total of 19 persons performing moderate complexity testing. 2. Review of personnel records revealed that there was no documentation to show that personnel performing total protein testing had a minimum of either a high school diploma or Graduate Equivalency Degree (GED) for 1 of 19 testing personnel listed on FORM-CMS 209. See Dtag 6065 3. At 11:00 AM on 06/12/19, the Center Manager confirmed the surveyor's findings.</p>
D6053	<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 semiannually during the first year the individual tests patient specimens.</p>

This STANDARD is not met as evidenced by:
Based on review of presurvey records, Laboratory Personnel Report (FORM CMS 209), personnel records and interview; the technical consultant failed to be 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. Findings include: 1. Review of presurvey records from the survey in January 2018 and FORM CMS 209, revealed that 16 of 19 testing personnel were new testing personnel in the laboratory, while 3 of 19 older testing personnel were testing in January 2018. 2. Review of personnel records revealed that there was no definitive "start date" documented for 19 of 19 moderate complexity testing personnel listed on FORM CMS 209. 3. There was no documentation to show a 6-month evaluation was performed for the following testing personnel: a. TP# 3 Evaluations performed 11/29/17 and 03/24/19 b. TP# 5 Evaluations performed 10/26/17 and 03/24/19 3. At 11:00 AM on 06/12/19, the Center Manager confirmed the surveyor's findings.

D6054

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 annually, after the first year.

This STANDARD is not met as evidenced by:
Based on review of presurvey records, Laboratory Personnel Report (FORM CMS 209), personnel records and interview; the technical consultant failed to be 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. Findings include: 1. Review of presurvey records from the survey in January 2018 and FORM CMS 209, revealed there were 16 new personnel and 3 old personnel listed on the form for a total of 19 testing personnel. 2. Review of personnel records revealed that there was no documentation to show that a competency assessment was performed in 2018 for 2 of 3 older testing personnel. The records were as follows: a. TP# 3 Evaluations performed 11/29/17 and 03/24/19 b. TP# 5 Evaluations performed 10/26/17 and 03/24/19 3. At 11:00 AM on 06/12/19, the Center Manager confirmed the surveyor's findings.

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(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

This STANDARD is not met as evidenced by:

Based on review of laboratory policies, procedures, personnel records and interview; testing personnel failed to meet the minimum educational requirement for performing total protein testing. Findings include: 1. Laboratory policies and procedures included modules titled, "Introduction to CLIA," Module slide # 5 states, " In order to work at the center as testing personnel, and individual must have a minimum of a high school diploma, GED or proof of equivalency if the employee has a foreign education record." 2. Review of Laboratory Personnel Report (FORM -CMS 209) revealed that the laboratory listed a total of 19 persons performing moderate complexity testing. 3. Review of personnel records revealed that there was no documentation to show that personnel listed on FORM-CMS 209 (person #9 listed on the 209) had the minimum education requirements (high school diploma or Graduate Equivalency Degree (GED)). 4. At 11:00 AM on 06/12/19, the Center Manager confirmed the surveyor's findings.