

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2115637	(X3) Date Survey Completed 10/27/2020
Name of Provider or Supplier Csl Plasma Inc	Street Address, City, State 6862 Highway 6 S, Ste 124, Houston, 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	<p>Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on the laboratory's American Association of Bioanalysts (AAB) proficiency testing records from 2018 to 2020 and interview with facility staff, the laboratory director failed to sign the attestation in 1 of 7 events. The findings were: 1. Review of the laboratory's AAB proficiency testing records from 2018 to 2020, revealed the laboratory's director failed to sign the attestation sheet for 2018 second event. 2. In interview with facility staff on 10/27/2020 at 1110 hours, confirmed the findings the attestation was not signed.</p>
D2011	TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(3)

Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample (s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's American Association of Bioanalysts (AAB) proficiency testing results from 2018 events 2 and 3, 2019 events 1, 2, and 3 and 2020 events 1 and 2, and staff interview, it was revealed the laboratory failed to have documentation of the review of proficiency testing results for 1 of 7 events. The findings were: 1. A review of the laboratory's AAB proficiency testing results from 2018 revealed the laboratory failed to have documentation of the review of proficiency testing results for 1 of 3 events. 2018 Event 2 3. An interview with the facility staff on 10/27/2020 at 1145 hours in the training room, confirmed the findings.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's submitted Listing of Laboratory Personnel form, review of the laboratory's personnel records, and staff interview, it was revealed the technical consultant failed to document authorization to test 2018 of one testing personnel prior to performing moderate complexity testing. The findings were: 1. A review of the laboratory's submitted Listing of Laboratory Personnel form revealed a competency assessment was performed for TP#3 on page 7 of 7 (hire date 03/21/2018, training 04/08/2108 and competency 04/08/2018). 2. A review of the laboratory's competency assessment records revealed the laboratory failed to document sign off authorization to test on TP #3 on page 7 of 7. Initial Competency performed on 04/08 /2020 Annual Competency performed 07/22/2019 3. An interview with the technical consultant on 10/22/2020 at 1505 hours in the testing office revealed there was no documentation of the technical consultant performing authorization to test on one testing personnel. This confirmed the above findings. Key TP -Testing Person

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 laboratory's personnel records and staff interview, it was revealed the technical consultant failed to performed competency assessments twice annually for 1 of 8 testing personnel within their first year of employment. The findings were: 1. A review of the laboratory's submitted Listing of Laboratory Personnel form revealed the laboratory identified one testing personnel identified as: Testing person #3 on page 7 of 7 hired 3/21/2018 2. Further review of the records revealed the laboratory had documentation of one competency assessment being performed. Competency was completed on 04/08/2018. 3. A review of the laboratory's personnel records revealed the laboratory failed to document twice annual competency assessment in the first year of testing. Testing person #3 on page 7 of 7 Initial Competency performed on 04/08/2020 Annual Competency performed 07/22 /2019 4. The laboratory was asked to provide documentation of performing a second competency assessment on testing personnel #3 in the first year. No second competency was documented in their file. 5. Interview with facility staff on 10/27 /2020 at 1345 hours confirmed the findings.