

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2239722	(X3) Date Survey Completed 05/26/2022
Name of Provider or Supplier Csl Plasma	Street Address, City, State 2800 S Ih 35 Suite 210, Round Rock, 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	The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D6066	<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 laboratory's policies and procedures, educational credentials, documentation of training and interview, the laboratory failed to ensure training was performed by the facility for testing personnel prior to performing patient testing for total protein using the Reichert TS Meter - DSP refractometer for two of 11 testing personnel (two of two transfer employees). Findings follow. A. Review of the laboratory's policy and procedure titled Reception - CLIA Activities Learning Capsule, Version 5.0 doc net effective May 13, 2022, stated "Curriculum covers the finger-stick, total protein, hematocrit, and refractometer activities" and listed the following training activities: Course titled Introduction to CLIA Course titled Digital Refractometer Activities Course titled Fingerstick and Hematocrit Course titled Total Protein Performance of CLIA Reception Activities - Complete Digital Refractometer Activities Performance of CLIA Reception Activities - Document Digital Refractometer Activities B. Review of educational credentials and training records showed transfer employees had training records from a sister facility. 1. Testing personnel #6 as listed on the CMS form 209, hired 4/18/2021, had a high school diploma with documentation of training for total protein using the refractometer from a sister facility in San Antonio. The training documents from a sister facility included the following: Course titled Introduction to CLIA 8/17/2020 Course titled Digital Refractometer Activities 8/17/2020 Course titled Fingerstick and Hematocrit 8/17/2020 Course titled Total Protein 8/17/2020 Performance of CLIA Reception</p>

Activities - Complete Digital Refractometer Activities 6/12/2020 2. Testing personnel #8, hired 6/13/2021, had a high school diploma with documentation of training for total protein using the refractometer from a sister facility in San Antonio. The training documents from a sister facility included the following: Course titled Introduction to CLIA 8/17/2020 Course titled Digital Refractometer Activities 8/17/2020 Course titled Fingerstick and Hematocrit 8/17/2020 Course titled Total Protein 8/17/2020 Performance of CLIA Reception Activities - Complete Digital Refractometer Activities 4/22/2020 C. Interview with the Assistant Manager of Quality on May 26, 2022 at 1000 in the conference room acknowledged training documents looked different for these employees because they transferred from another facility and their training documents were performed at the other facility. The Technical Consultant Observation Worksheet (competency evaluations) were performed initially and at 6 months. Further interview with the Assistant Manager of Quality on May 26, 2022 at 1245 in the conference room confirmed training was performed at another site, and initial competency was assessed at this location, it's just the training that is not repeated. NOTE: Training was not performed at the facility where testing was conducted for transfer employees.