

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1098041	(X3) Date Survey Completed 01/19/2022
Name of Provider or Supplier Octapharma Plasma, Inc	Street Address, City, State 7006 University Avenue Unit13, Lubbock, 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
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 policy and procedure, 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 refractometer for one of 28 testing personnel (one of one transfer employees). Findings follow. A. Review of the laboratory's policy and procedure titled Training Policies - NexLynk on page 4 under 5.2 Employee Training Folders and 5.2.2. Transferred Employees stated, "5.2.2.3. Employees who have completed Medical Screener - Return Donors training and permanently transfer to another donor Center must complete a Moderate Complexity [competency] with their transferred center's CLIA Director." B. Review of educational credentials and training records showed testing personnel #23, as listed on the CMS Form 209, hired 09/08 /2021, had a high school diploma with no documentation of training for total protein using the refractometer. C. Interview with the Quality Assurance Supervisor on January 19, 2022 at 1115 in the office acknowledged there was no documentation of training for testing personnel #23 because they would have to request the documentation of training from their sister facility. He confirmed they do not perform their own training on transfers, and it is not stated in their policy for them to do so. NOTE: Training was not performed at the facility where testing was conducted for transfer employees.</p>